

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

SKANDIA MUTUAL LIFE INSURANCE CO.,  
LÄNSFÖRSÄKRINGAR AB, KBC ASSET  
MANAGEMENT NV, and GIC PRIVATE  
LIMITED,

Plaintiffs,

v.

VIATRIS INC. F/K/A/ MYLAN N.V.,  
HEATHER BRESCH, RAJIV MALIK,  
KENNETH S. PARKS, ANTHONY MAURO,  
and JAMES NESTA.

Defendants.

CIVIL ACTION NO: \_\_\_\_\_

COMPLAINT

**JURY TRIAL DEMANDED**

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Plaintiffs Skandia Life Insurance Co. (“Skandia”), KBC Asset Management NV (“KBC”), Länsförsäkringar AB (“Länsförsäkringar”), and GIC Private Limited (“GIC”) (collectively, “Plaintiffs”), by their undersigned counsel, make the following allegations upon personal knowledge as to their own acts and upon information and belief as to all other matters. Plaintiffs’ information and beliefs are based on, *inter alia*, an investigation by their attorneys, which investigation includes, among other things, a review and analysis of: Mylan N.V. (“Mylan”)<sup>1</sup>’s filings with the United States Securities and Exchange Commission (“SEC”); Mylan’s public documents; reports concerning Mylan in the media and in business publications; analyst reports concerning Mylan; transcripts of conference calls and earnings calls involving Mylan, Heather Bresch, Rajiv Malik, Kenneth S. Parks, Anthony Mauro, and/or James Nesta (collectively, “Defendants”); orders, pleadings, motion papers, and exhibits to declarations filed in the matter *In re Mylan N.V. Securities Litigation*, 16-cv-07926 (JPO) (S.D.N.Y.) (the “S.D.N.Y. Mylan Class Action”); orders, pleadings, motion papers, and exhibits to declarations filed in the matter *Public Employees’ Retirement System of Mississippi v. Mylan N.V. et al.*, 20-cv-00955 (W.D. Pa.) (the “W.D. Pa. Mylan Class Action”); orders, pleadings, motion papers, and exhibits to declarations filed in the matter *State of Connecticut v. Teva Pharmaceuticals*, No. 3:19-cv-00710-MPS (D. Conn) (the “Connecticut Teva Action”); and government investigations and reports.

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<sup>1</sup> In November 2020, Mylan N.V. merged with Pfizer Inc.’s Upjohn business, resulting in a new entity, Viatris Inc. This Complaint relates to activities and conduct during the Relevant Period by the former entity known as Mylan N.V., and references herein to “Mylan” and/or “the Company” are to the entity formerly known as Mylan N.V.

## INTRODUCTION

1. Plaintiffs bring this action (the “Action”) under the Securities Exchange Act of 1934 (the “Exchange Act”) against Defendants to recover damages for losses Plaintiffs suffered in connection with their acquisition of Mylan securities between February 16, 2016 and May 24, 2019, both dates inclusive (the “Relevant Period”). Plaintiffs purchased or otherwise acquired Mylan securities at artificially inflated prices during the Relevant Period and suffered damages as a result of the violations of the Exchange Act alleged herein.

2. At all relevant times, Mylan was the second largest generic drug manufacturer in the world, with roughly 55 manufacturing and research and development (“R&D”) facilities globally. During the Relevant Period, Mylan’s largest U.S. manufacturing facility was located in Morgantown, West Virginia. Mylan manufactured and sold, among other products, the EpiPen Auto-Injector® and EpiPen Jr Auto-Injector® (collectively, the “EpiPen”), a branded drug that allows the user to auto inject a measured dose of epinephrine to treat anaphylaxis, a life-threatening emergency to which one in thirteen children is susceptible. Mylan also manufactured and sold the following generic drugs, among others: albuterol sulfate, used to treat asthma and other lung conditions; benazepril, used to treat high blood pressure; clomipramine, a tricyclic antidepressant used to treat obsessive compulsive disorder, a potentially debilitating mental illness; divalproex, used to treat certain types of seizures and migraines; doxycycline hydiate delayed release (“Doxycy DR”), a tetracycline antibiotic used to treat a wide range of bacterial infections, including severe respiratory infections and anthrax; and propranolol, a beta-blocker used to treat and prevent heart attacks and other heart and circulatory conditions.

3. The U.S. Food and Drug Administration (“FDA”) regulated Mylan through quality-control regulations called Current Good Manufacturing Practices (“CGMP”). “Data

integrity” requirements, which are designed to ensure that quality and safety testing is complete, accurate, and free from manipulation, are a core component of CGMP. As Mylan itself repeatedly acknowledged, compliance with CGMP regulations, including data integrity requirements, was critical to the Company’s business and profitability. If the FDA discovers serious CGMP violations, it may effectively freeze a drug manufacturer’s operations, require recalls, and order extensive remedial action that may involve extensive costs and prolonged disruptions to production.

4. Over the past two decades, in over a dozen matters, Mylan has been repeatedly investigated by the Federal Trade Commission (“FTC”), the Department of Justice (“DOJ”), the SEC, and the FDA, and has been sued by private litigants for fraudulently overcharging Medicaid for its drug purchases, for illegal price manipulation, for entering into illegal anticompetitive agreements, and for violating key FDA regulations governing product quality and safety, including at the Company’s flagship drug manufacturing facility in Morgantown, West Virginia.

5. Through the conduct described in this Complaint, Mylan impugned the integrity of its procedures and made lifesaving drugs less available to children, the elderly, and other ordinary Americans who struggle to afford these drugs.

6. Plaintiffs bring this Action because, during the Relevant Period, Defendants misled Plaintiffs about: (i) a course of conduct intended to cheat Medicaid (the U.S. low-income healthcare program) out of its rightful rebates for EpiPen purchases; (ii) anticompetitive conduct to exclude competition that allowed Defendants to inflate the price of EpiPen astronomically, beyond the reach of many consumers; (iii) a scheme to inflate the prices of critical generic drugs by over 1000% by engaging in numerous anticompetitive activities; and (iv) violations of key

FDA regulations governing product quality and safety, including at the Company's flagship drug manufacturing facility in Morgantown, West Virginia.

7. In particular, Defendants: (i) systematically and knowingly misclassified the EpiPen as a generic drug in order to overcharge Medicaid by hundreds of millions of dollars for its purchases of this life-saving device for Medicaid recipients; (ii) entered into exclusive dealing arrangements with commercial insurance companies and pharmaceutical benefit managers in order to prevent competitor Sanofi-Aventis U.S. LLC ("Sanofi") from successfully introducing a product to compete with EpiPen; (iii) Mylan entered into, and maintained, anticompetitive agreements with its "competitors" to allocate the market and fix the prices for virtually all of Mylan's generic drugs including, but not limited to Doxy DR, fenofibrate, clonidine-TTS Patch, tolterodine extended release, capecitabine, enalapril, valsartan HCTZ, albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, amiloride HCL/HCTZ, doxazosin mesylate, ketorolac, loperamide HCL, levothyroxine, methotrexate, nadolol, tizanidine, trifluoperazine HCL, budesonide DR, buspirone hydrochloride, cimetidine tablets, diclofenac potassium, diltiazem HCL, estradiol, fluoxetine HCL, flurbiprofen, fluvastatin sodium, haloperidol, ketoconazole, ketoprofen, nitrofurantoin MAC capsules, pentoxifylline, prazosin HCL, prochlorperazine, tamoxifen citrate and tolmetin sodium; and (iv) engaged in a scheme to corrupt quality control data files by bypassing countless expensive and time-consuming quality control tests and allowing for massive drug production volume at decreased costs.

8. *First*, as soon as Mylan acquired the rights to market the EpiPen, Mylan knowingly misclassified the EpiPen as a generic drug in order to improperly reduce the size of the rebates that it owed Medicaid. Although Mylan externally marketed the EpiPen as a brand-name drug and federal law required Mylan to classify the EpiPen as a brand-name drug for

purposes of the Medicaid rebate, Mylan calculated the rebate on the EpiPen as if it were a generic drug. By paying Medicaid a smaller rebate, Mylan was able to inflate the revenues and profits that it recorded from sales of the EpiPen. This intentional misclassification of the EpiPen by Mylan cost U.S. taxpayers – who fund Medicaid – over a billion dollars.

9. Indeed, before the Relevant Period, the Centers for Medicare & Medicaid Services (“CMS”), expressly notified Mylan that the EpiPen was misclassified, as the Acting Administrator Andrew M. Slavitt confirmed in correspondence with the U.S. Senate. In early 2009, the Inspector General of the U.S. Department of Health and Human Services (“HHS”) expressly told CMS that the EpiPen was misclassified for the purposes of the Medicaid Drug Rebate Program (“MDRP”). Thereafter, on multiple occasions, CMS expressly notified Mylan that the EpiPen was misclassified. As Acting Administrator Slavitt stated in an October 5, 2016 letter to Senator Ron Wyden, “CMS has, on multiple occasions . . . expressly told Mylan that the product [EpiPen] is incorrectly classified.”

10. Mylan also repeatedly misrepresented that there was no investigation into its classification of the EpiPen when in fact the DOJ had launched just such an investigation in November 2014. Mylan is independently liable for these misrepresentations.

11. Also unbeknownst to investors, Mylan engaged in anticompetitive conduct to control the market for epinephrine auto-injectors. Specifically, Mylan paid large rebates to Pharmacy Benefit Managers (“PBMs”) to ensure that potential competitors to the EpiPen were not covered by a patient’s prescription drug plan. Thus, patients who needed an epinephrine auto-injector had to either accept the EpiPen or pay out-of-pocket for another epinephrine auto-injector. By engaging in this anticompetitive conduct, Mylan was able to maintain an effective

monopoly over the epinephrine auto-injector market, which in turn allowed Mylan to drastically raise the price of the EpiPen from less than \$100 to over \$600.

12. For example, in 2013, Sanofi attempted to introduce a competitor to the EpiPen, called the Auvi-Q. The Auvi-Q was a serious threat to Mylan's control of the market. Sanofi offered the Auvi-Q at around the same price as the EpiPen, but the Auvi-Q had certain advantages over the EpiPen, including the ability to provide a recorded voice instruction on how to administer the Auvi-Q. In response to this competitive threat, Mylan began to offer unprecedented rebates of 30% or more on the cost of the EpiPen to third-party payors, including commercial insurance companies and PBMs. As a result of its anticompetitive conduct, Mylan successfully blocked Auvi-Q from accessing nearly 50% of the U.S. market for epinephrine autoinjectors. In certain states where Mylan's exclusionary rebates were particularly pervasive, Sanofi's Auvi-Q was blocked from significantly more than 50% of the market.

13. Defendants made material misrepresentations and failed to disclose material information about Mylan's marketing and sale of the EpiPen. Defendants did this by: (i) purporting to provide explanations in Mylan's SEC reports about how the EpiPen contributed to Mylan's financial performance, but without apprising the market that these figures were grossly inflated because Mylan had not paid hundreds of millions of dollars in rebates that it owed to Medicaid as a result of its intentional misclassification of the EpiPen; (ii) misleading the investing public that Mylan was paying the correct rebate amount to Medicaid for the EpiPen when, in fact, Mylan was drastically underpaying Medicaid the rebates it owed on EpiPen sales funded by U.S. taxpayers; (iii) lying to investors about Defendants' knowledge of the EpiPen misclassification; (iv) cautioning the market that improper classification of the EpiPen could lead to regulatory scrutiny without informing investors that Mylan was under investigation already for

misclassifying the EpiPen; and (v) falsely asserting that the market for the EpiPen was very competitive without disclosing the anticompetitive conduct in which Mylan was engaging with respect to the EpiPen.

14. When these frauds concealed by Defendants became known to the investing public, Mylan’s stock dropped precipitously. In late August 2016, a news article detailed how Mylan had increased the price of the EpiPen over 500%, revealing the effects of Mylan’s anticompetitive conduct and causing a public outcry. U.S. Congresspersons then called on Congress and the FTC to investigate Mylan for anticompetitive conduct relating to the EpiPen. Upon this news and other related revelations, Mylan’s stock price fell \$6.17, or 12.51%, between August 19 and August 24, 2016. When the FTC announced, on January 30, 2017, that it was investigating Mylan, Mylan’s stock price fell even further.

15. *Second*, unbeknownst to investors, prior to the Relevant Period, Mylan entered into anticompetitive agreements with its competitors in the generic drug market to allocate the market for, and to fix the prices of, the generic drugs it sold. For many years, the generic pharmaceutical industry, and Mylan as a key member of that industry, operated pursuant to an understanding among generic manufacturers not to compete with each other and to instead settle for what these competitors refer to as a “fair share.” The purpose of the agreement was to avoid competition among generic manufacturers that would normally result in significant price erosion and great savings to the ultimate consumer. This understanding has permeated every segment of the industry—it covered not merely a select few drugs, but rather the entirety of Mylan’s generic drug business. Rather than enter a particular generic drug market by competing on price in order to gain market share, competitors in the generic drug industry, including Mylan, systematically and routinely communicated with one another directly, divvied up customers to create an

artificial equilibrium in the market, and then maintained anticompetitively high prices. This “fair share” understanding was not the result of independent decision making by individual companies to avoid competing with one another. Rather, it was a direct result of specific discussion, negotiation and collusion among virtually all industry participants, led in part by Mylan, over the course of many years.

16. Beginning in 2012, Mylan and its co-conspirators embarked on one of the most egregious and damaging price-fixing conspiracies in United States history. Mylan and its competitors sought to leverage the collusive nature of the industry to not only maintain their “fair share” of each generic drug market, but also to significantly raise prices on as many drugs as possible. In order to accomplish that objective, Mylan and its competitors with which it already had very profitable collusive relationships—referred to among the co-conspirators as “High Quality” competitors—decided to raise the prices in the markets for drugs the co-conspirators jointly dominated. Mylan had understandings with its highest quality competitors to lead and follow each other’s price increases, and did so with great frequency and success. This resulted in many billions of dollars of harm to the national economy over a period of several years in what the assistant attorney general of Connecticut described as “likely the largest cartel in the history of the United States.”<sup>2</sup>

17. The evidence that Mylan engaged in this anticompetitive conduct is overwhelming. On December 14, 2016, the attorneys general of twenty states (the “20 States”) filed a joint complaint against Mylan that was the product of a years-long investigation.<sup>3</sup> The

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<sup>2</sup> Christopher Rowland, “Investigation of Generic ‘Cartel’ Expands to 300 Drugs,” Wash. Post, Dec. 8, 2018 (quoting Joseph Nielsen).

<sup>3</sup>According the Third Amended Complaint in the S.D.N.Y. Mylan Class Action, counsel for lead plaintiffs in the S.D.N.Y. Mylan Class Action contacted the Connecticut Attorney General’s Office regarding the allegations set

complaint was amended, on June 18, 2018, to add attorneys general alleging violations of federal and state antitrust laws, as well as violations of various states' consumer protection laws. The amended complaint also includes claims asserted by attorneys general of thirty-seven states and the Commonwealth of Puerto Rico against certain individuals, including Mylan's President, Defendant Rajiv Malik. Likewise, on May 10, 2019, the attorneys general of over 40 states (the "46 States") filed the Connecticut Teva Action against Mylan and other generic drug companies for antitrust violations.<sup>4</sup> In the complaints, the 46 States tell the story, with great detail and relying on documentation, of how Mylan agreed to allocate the markets of numerous generic drugs with its competitors.

18. The evidence that Mylan colluded to fix the price of generic drugs is likewise clear. The average prices of these drugs in the United States moved in near-perfect unison during the period of the conspiracy, and the prices of these drugs increased suddenly and simultaneously at each drug company at or near the start of that period. The price increases were exponential—the prices of multiple drugs, including, for example, clomipramine and propranolol, increased

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forth in the Connecticut Attorney General's Complaint filed on December 14, 2016, *see Connecticut v. Aurobindo Pharma USA, Inc.*, No. 3:16-cv-02056 (D. Conn. Dec. 14, 2016), Dkt. No. 1, and the [Proposed] Consolidated Amended Complaint filed on October 31, 2017, *see Connecticut v. Aurobindo Pharma USA, Inc.*, No. 2:17-cv-03768 (E.D. Pa. Oct. 31, 2017), Dkt. No. 3. A signatory of the Connecticut Attorney General's Complaint and [Proposed] Consolidated Amended Complaint confirmed to counsel in the S.D.N.Y. Mylan Class Action that the documents cited in those Complaints included documents produced by Mylan, and that the Connecticut Attorney General's Office has evidentiary support for its allegations against Mylan and Defendant Malik.

<sup>4</sup> *See* Complaint, *State of Connecticut v. Teva Pharmaceuticals*, No. 3:19-cv-00710-MPS (D. Conn. May 10, 2019), Dkt. No. 1 (the "Connecticut Teva Complaint"). According to the Third Amended Complaint in the S.D.N.Y. Mylan Class Action, a signatory of the Connecticut Teva Complaint at the Connecticut Attorney General's Office confirmed that the Office has evidentiary support for the allegations contained in the Connecticut Teva Complaint, including documents, emails, phone records, and the testimony of cooperating witnesses. According to Third Amended Complaint in the S.D.N.Y. Mylan Class Action, a second individual, the Deputy Director of Communications for the Attorney General in Connecticut, likewise confirmed that the Connecticut Teva Complaint is based on the facts gathered in the states' investigation and that, to her knowledge, "everything in the [Connecticut Teva] Complaint is factual."

suddenly by over 1000%. No other explanation for these sudden, synchronized price increases exists—there was no supply shortage or sudden increase in demand for these drugs during this period. Moreover, the market for generic drugs is highly susceptible to collusion for a number of reasons detailed below. For example, the markets for the Price-Fixed Drugs<sup>5</sup> are dominated by only a few companies, and this market concentration makes collusion easy. The extreme price increases caused by this generic drug price-fixing cartel, in which Mylan is an active and important player, imposed, and continue to impose, a searingly unfair burden on nearly all residents of the United States, including children and the elderly, who, without exaggeration, rely on affordable generic drugs for their quality of life, and in some cases, their survival.

19. Mylan again misled investors about the competition it faced and about the validity of its sales figures. Mylan repeatedly stated to investors that the market for generic drugs was highly competitive. In fact, the market for at least some of the generic drugs Mylan sold was collusive, and lacked any real competition. Mylan’s statements about the basis for its financial performance were also misleading because they failed to disclose that Mylan competed through anticompetitive means, and so failed to tell the whole truth about the bases for Mylan’s financial success. Mylan’s statements suggested that it did not compete through collusion with competitors on prices, when in fact it did, and while Mylan’s collusion certainly violated U.S. antitrust laws, investors cared about such collusion in any event due to the significant liability to which it exposed Mylan.

20. On October 31, 2017, the Attorney General of the State of Connecticut issued a press release on behalf of the 46 States in which he announced that the group would be filing an

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<sup>5</sup> The “Price-Fixed Drugs,” include, but are not limited to, the generic drugs albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, amiloride HCL/HCTZ, doxazosin mesylate, ketorolac, loperamide HCL, levothyroxine sodium, methotrexate, nadolol, tizanidine, and trifluoperazine HCL.

amended complaint in the Connecticut Teva Action against Mylan and attached the proposed amended complaint. The amended complaint contained extensive new allegations that Mylan participated in a wide-ranging price-fixing conspiracy, and for the first time named Defendant Rajiv Malik, Mylan’s President and executive director, as an individual defendant for his direct participation in the conspiracy. The amended complaint also contained additional details regarding the conspiracy between Mylan and other drug companies to allocate the market and fix the price of generic drugs. On this news, Mylan’s share price fell \$2.53, or 6.62%, to close at \$35.71 on October 31, 2017.

21. *Third*, Mylan concealed egregious violations of key FDA regulations governing product quality and safety, including at the Company’s flagship drug manufacturing facility in Morgantown, West Virginia. The Company’s Morgantown, West Virginia campus was Mylan’s largest and most significant manufacturing facility in the world; in fact, it was one of the largest pharmaceutical manufacturing facilities in the entire United States during the Relevant Period. The Morgantown plant was critical to the Company’s largest business segment—its North American business—and manufactured approximately 85% of the oral solid doses of medicine Mylan sold in the United States during the Relevant Period.

22. In September 2015, prior to the Relevant Period, a former Mylan employee turned whistleblower disclosed to the FDA that, under the direct leadership of Defendant Malik, Mylan employees had been manipulating drug test results to achieve passing quality control results. The whistleblower told the FDA that Mylan employees were deliberately and routinely corrupting testing data by, among other techniques, intentionally crashing Mylan testing computers to evade FDA detection.

23. On November 7, 2016, after receiving the whistleblower complaint, inspectors arrived unannounced at Mylan’s Morgantown facility to conduct an 11-day investigation. When they arrived at Morgantown, the investigators discovered that the Company was systematically using a host of suspect data practices to avoid reporting failing quality control testing results that could trigger lengthy production delays or even product recalls. The FDA found thousands of random files containing what appeared to be forbidden exploratory tests, a tactic some drug-makers have used to prevent quality failures from coming to light. The FDA also found bins full of shredded documents, including quality-control records, in parts of the facility where such documentation is supposed to be preserved. The FDA suspected Mylan laboratory staff had recorded passing scores on drugs that originally fell short of U.S. quality standards. The FDA warned Defendants that Mylan routinely engaged in a highly improper practice known as “testing into compliance,” which involves repeatedly retesting drug products that had failed quality testing in order to achieve passing results—and is specifically prohibited under FDA guidance. As a result, on November 18, 2016, the FDA privately issued to Mylan a 23-page citation detailing these findings. The FDA’s extensive and thorough criticisms put Defendants on notice that the Company would need to immediately begin extensive remediation, including significantly reducing Morgantown’s unrealistic production volumes, and that it faced a serious risk of further adverse regulatory action. Nevertheless, according to the Amended Complaint in the W.D. Pa. Mylan Class Action, former employees reported that Defendant Malik continued to insist on cuts to Morgantown’s quality budget, rather than the material expansion of the budget called for by the FDA’s findings.

24. Even after receiving the FDA’s scathing inspection report—called a Form 483—Defendants continued to receive clear and direct warnings that Morgantown suffered from severe

quality control issues. Moreover, during the Relevant Period, Mylan was forced to recall numerous drug products manufactured at Morgantown, including drugs cited in the FDA’s 2016 Form 483. Nevertheless, Defendants continued to misleadingly tout Mylan’s “advanced” and comprehensive quality control processes and the Company’s commitment to CGMP compliance.

25. On April 3, 2017, Mylan received a warning letter from the FDA concerning one of its India plants, detailing nearly identical data corruption issues and other violations that paralleled those described in the FDA’s November 2016 Form 483 directed to Mylan’s Morgantown plant. A full month later, on May 10, 2017, during Mylan’s first quarter 2017 earnings conference call, Defendant Malik downplayed the letter as reflecting a discrete set of oneoff technical issues that were confined to just one of Mylan’s plants. Defendant Malik stated that Mylan was “dedicated to continually enhancing our systems and processes, with a deliberate and thorough approach to ensure sustainable quality across our entire network of facilities, working closely with FDA to resolve any issues that come our way.” Indeed, Defendant Malik boasted that inspections of Mylan’s remaining facilities had all been successful. Defendant Malik failed to disclose the Form 483 issued to the Company’s far more significant Morgantown facility or the financial and regulatory risk it entailed, despite the fact that just weeks earlier, FDA officials told Defendant Malik directly that Morgantown’s failures were “egregious” and raised serious questions about the integrity of the Company’s products.

26. On April 20, 2018, Mylan announced it would be restructuring its Morgantown plant, including by terminating 500 employees. Mylan stated that the “Morgantown plant needed to be right-sized to be less complex” due to general “industry” changes. While Mylan’s statement asserted that these changes are “consistent with discussions we are having with the [FDA],” Mylan did not elaborate on the substance of those discussions or indicate that the

restructuring was related to the significant violations identified by the FDA. Investors, including Plaintiffs, did not know that beginning in early 2018, a whistleblower inside the Morgantown facility privately told the FDA that, instead of working to remedy problems identified in the 2016 Form 483, Mylan was more focused on creating a “façade of documents” to fend off the agency and, as a result, product quality was continuing to deteriorate rather than improve. The whistleblower further told the FDA that Mylan had developed an “embedded culture” of fraud. In response, the FDA conducted another surprise inspection of Morgantown in March 2018, and its findings corroborated the whistleblower’s report.

27. Following its inspection, the FDA issued Mylan the second Form 483 related to Morgantown in less than two years, citing the same egregious CGMP and data integrity violations about which Defendants and other members of Mylan’s senior leadership had been repeatedly warned, including in Morgantown’s 2016 Form 483. Among other things, the FDA found that Mylan’s improper practice of invalidating failing results and re-testing drug products without adequate investigation was still widespread and that Mylan’s “senior management” had failed to exercise appropriate quality control oversight. In a subsequent warning letter issued to Mylan, the FDA made clear that the agency had repeatedly warned the Company that its practice of “testing into compliance” was improper, stating that “the unjustified invalidation of failing test results is a repeat violation.” Moreover, the FDA emphasized that the seriousness, pervasiveness, and duration of the violations left little doubt that Mylan’s senior management was directly responsible: “These repeated failures at multiple sites demonstrate that Mylan’s management oversight and control over the manufacture of drugs is inadequate . . . . Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.”

28. Significantly, following the 2018 inspection, Defendants admitted in private correspondence with the FDA that “the large volume of doses and products within the Morgantown portfolio . . . inhibited [Mylan’s] ability to achieve the high level of control over our manufacturing processes that we expect.”

29. Accordingly, after the FDA’s 2018 Morgantown inspection, Mylan was finally compelled to take meaningful remedial measures, as it should have done even before the start of the Relevant Period. First, Mylan was forced to halt production at the facility in order to prevent the release of adulterated products. Second, Mylan was forced to dramatically reduce Morgantown’s overwhelming production volume. Third, Mylan was forced to implement extensive remedial measures under consultant supervision. As a result of these steps, Mylan’s sales declined, and expenses increased, respectively, by at least hundreds of millions of dollars.

30. As the relevant truth about Mylan’s widespread CGMP and data integrity violations was finally revealed to investors, Mylan’s stock price declined precipitously, wiping out billions in shareholder value.

31. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of Mylan’s securities, Plaintiffs and other investors suffered significant losses and damages.

#### **JURISDICTION AND VENUE**

32. The claims asserted herein arise under and pursuant to Sections 10(b), 18, and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78r, and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

33. This Court has jurisdiction over the Exchange Act claims pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1331.

34. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). At all relevant times, Mylan's stock traded on the NASDAQ-GS, located within this Judicial District. Many of the acts giving rise to the violations complained of herein, including the dissemination of false and misleading information, occurred in this District.

35. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mails, interstate telephone communications, and the facilities of national securities exchange and market.

## **PARTIES**

### **I. Plaintiffs**

#### **A. Skandia**

36. Skandia is a financial services company located in Stockholm, Sweden. Skandia purchased shares of Mylan common stock during the Relevant Period following Defendants' issuance of false and/or misleading statements as detailed herein at prices that were artificially inflated as a result of Defendants' misconduct. Skandia held many of those shares at the times of the corrective disclosures and resulting stock price declines referenced herein, thereby suffering damages as a result of the misconduct alleged herein.

#### **B. Länsförsäkringar**

37. Länsförsäkringar is an insurance company located in Stockholm, Sweden. Länsförsäkringar purchased shares of Mylan common stock during the Relevant Period following Defendants' issuance of false and/or misleading statements as detailed herein at prices that were artificially inflated as a result of Defendants' misconduct. Länsförsäkringar held many

of those shares at the times of the corrective disclosures and resulting stock price declines referenced herein, thereby suffering damages as a result of the misconduct alleged herein.

**C. KBC**

38. KBC is an investment manager in Brussels, Belgium. KBC purchased shares of Mylan common stock during the Relevant Period following Defendants' issuance of false and/or misleading statements as detailed herein at prices that were artificially inflated as a result of Defendants' misconduct. KBC held many of those shares at the times of the corrective disclosures and resulting stock price declines referenced herein, thereby suffering damages as a result of the misconduct alleged herein.

**D. GIC**

39. GIC is a sovereign wealth fund that was incorporated in 1981 under the Singapore Companies Act and is wholly owned by the Government of Singapore. GIC is headquartered in Singapore and has ten offices worldwide, including one in New York. GIC purchased shares of Mylan common stock during the Relevant Period following Defendants' issuance of false and/or misleading statements as detailed herein at prices that were artificially inflated as a result of Defendants' misconduct. GIC held many of those shares at the times of the corrective disclosures and resulting stock price declines referenced herein, thereby suffering damages as a result of the misconduct alleged herein.

**II. Defendants**

**A. Viatris Inc. f/k/a Mylan N.V.**

40. Viatris Inc. ("Viatris") was formed on November 16, 2020 through the merger of Mylan N.V. and Pfizer Inc. ("Pfizer")'s Upjohn business in a Reverse Morris Trust transaction. Prior to the merger, Mylan N.V. was incorporated in the Netherlands. During the Relevant

Period, Mylan N.V., together with its subsidiaries, developed, licensed, manufactured, marketed, and distributed generic and specialty pharmaceuticals worldwide. Mylan N.V. was the second largest generic drug manufacturer in the world with roughly 55 manufacturing and research and development facilities globally. The Company provided generic pharmaceutical products in tablet, capsule, injectable, transdermal patch, gel, cream, or ointment forms, as well as active pharmaceutical ingredients. Among other products, Mylan N.V. marketed and sold the EpiPen, a branded device for injecting a measured dose of epinephrine by means of auto-injector technology to treat severe allergic reactions. As of May 7, 2019, Mylan N.V. had over 514 million shares of stock outstanding, owned by at least thousands of investors. Throughout the Relevant Period, Mylan N.V. traded on the NASDAQ-GS under the ticker symbol MYL. References to “Mylan” and/or “the Company” in this Complaint refer to Mylan N.V. prior to and during the Relevant Period, which was prior to the merger.

#### **B. The Individual Defendants**

41. Defendant Heather Bresch (“Bresch”) was appointed as Mylan’s Chief Executive Officer (“CEO”) in January 2012. Defendant Bresch served as Mylan’s CEO throughout the Relevant Period. Among other positions at Mylan, Bresch also served as President, Chief Operating Officer, and Chief Integration Officer. Defendant Bresch was a member of Mylan’s Board of Directors (the “Board”) throughout the Relevant Period. During the Relevant Period, Defendant Bresch signed Mylan’s Form 10-K’s filed with the SEC on February 16, 2016, March 1, 2017, March 1, 2018, and February 27, 2019, the Company’s proxy statement filed on May 24, 2017, and the Sarbanes-Oxley Act of 2002 (“SOX”) certifications filed with Mylan’s 2016 and 2017 Annual Reports and with Mylan’s Quarterly Reports for the First and Second Quarters of 2016, among other SEC filings.

42. Defendant Rajiv Malik (“Malik”) became Mylan’s President on January 1, 2012, and served as Mylan’s President throughout the Relevant Period. In addition, Defendant Malik served as an Executive Director of Mylan since 2013 and throughout the Relevant Period. Defendant Malik was responsible for the day-to-day operations of Mylan, including the Company’s Commercial, Scientific Affairs, Manufacturing, Supply Chain, and Quality divisions. During the Relevant Period, Defendant Malik signed Mylan’s Form 10-K’s filed with the SEC on February 16, 2016, March 1, 2017, March 1, 2018, and February 27, 2019, among other SEC filings.

43. Defendant Kenneth S. Parks (“Parks”) became Chief Financial Officer (“CFO”) of Mylan in June 2016, taking over the role from John D. Sheehan (“Sheehan”). Throughout the Relevant Period, Parks was responsible for all of Mylan’s global finance functions including accounting and control, financial planning and analysis, investor relations, treasury, and tax. During the Relevant Period, Defendant Parks signed the SOX certifications filed with Mylan’s 2017 Annual Report and Mylan’s Quarterly Report for the Second Quarter of 2016.

44. Defendant James Nesta (“Nesta”) served as Vice President of Sales and Vice President of National Accounts at Mylan throughout the Relevant Period.

45. Defendant Anthony “Tony” Mauro (“Mauro”) served as Mylan’s President of North America from January 1, 2012 to January 2016. During the Relevant Period, Defendant Mauro served as Mylan’s Chief Commercial Officer (“COO”).

46. Defendants Bresch, Malik, Parks, Mauro, and Nesta, are collectively referred to herein as the “Individual Defendants.”

## SUBSTANTIVE ALLEGATIONS

### **I. Mylan Misled Plaintiffs and Other Investors by Failing to Disclose that it Was Overcharging Medicaid for EpiPen and by Failing to Disclose that Mylan Was Being Investigated for its EpiPen Classification**

#### **A. The EpiPen**

47. During the Relevant Period, two of Mylan’s primary products were the EpiPen® (epinephrine injection, USP) Auto-Injector and the EpiPen Jr® (epinephrine injection, USP) (collectively, the “EpiPen”). The EpiPen is a device for injecting epinephrine into a person suffering from a severe allergic reaction. Individuals who are allergic to certain foods (and other allergens, such as bee stings) can suffer anaphylaxis when exposed to those substances. Symptoms of anaphylaxis include swelling, vomiting, and difficulty breathing. If left untreated, anaphylaxis can result in death.

48. Approximately 4.6% of people in the U.S. suffer from food allergies, including 1 in 13 children. Anaphylaxis can be treated by injecting a person having a severe allergic reaction with epinephrine. Epinephrine is manufactured adrenaline. Although epinephrine has been around for a long time, the EpiPen was the first device to allow patients to easily and quickly self-administer the medication with an auto-injector pen. An epinephrine injection must be administered immediately in order to be effective. As a result, doctors typically recommend that adults and the parents of children susceptible to anaphylaxis carry with them a prefilled epinephrine auto-injector, which is available only by medical prescription, such as the EpiPen.

49. Mylan acquired the rights to market and distribute the EpiPen from Merck KGaA (“Merck”) in 2007. There are numerous patents covering the EpiPen. These patents do not expire until September 2025.

## B. The Importance of EpiPen to Mylan's Business

50. Ever since Mylan first acquired the EpiPen in 2007, the EpiPen has been enormously important to Mylan's business. As illustrated in the following table, during the Relevant Period, the EpiPen was responsible for between 28% and 95% of Mylan's operating profits—*i.e.*, profit earned from Mylan's normal, core business operations.

Operating Profit by Year (millions USD) <sup>6</sup>					
	2012	2013	2014	2015	2016
EpiPen	306	393	525	498	671
Total Mylan	1,109	1,135	1,352	1,460	701
% From	27.59%	34.63%	38.83%	34.11%	95.64%

51. The EpiPen's paramount importance to Mylan is also reflected in analyst reports covering the Company, which, throughout the Relevant Period, devoted significant attention to the EpiPen and routinely tied Mylan's overall fortunes to the EpiPen.

52. For example, in a report dated August 24, 2016, RBC Capital Markets analyst Randall Stanicky noted that “the importance of [EpiPen] to [Mylan’s] P&L growth over the last several years has been well understood,” and that “EPIPEN has been an important growth driver for MYL the last several years.”<sup>7</sup> JPMorgan analyst Chris Schott similarly noted in an October 4,

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<sup>6</sup> EpiPen operating profits are taken from a September 2016 SEC filing made by Mylan specifically for the purpose of providing profitability information about the EpiPen, after Mylan gave testimony on that topic to Congress. That filing explained that “Mylan does not regularly provide profitability analyses for individual products and does not intend in the future to provide product level profitability [sic] analysis for EpiPen or to update this analysis.” The figure for 2016 is an estimated figure. Total Mylan operating profits are taken from Mylan’s Form 10-K’s, where they are reported as “Earnings from operations.”

<sup>7</sup> Randal Stanicky, Matthew Won & Ashley Ryu, *Our thoughts on negative EPIPEN pricing “headline”: Direct read to MYL but also implications for TEVA and IPXL*, RBC Capital Markets (Aug. 24, 2016).

2016 report that “EpiPen is Mylan’s largest product at >\$1bn in sales.”<sup>8</sup> In fact, Morningstar’s mere four-sentence profile of the company highlights the EpiPen by name, noting that after revenue from generics, “[r]emaining sales come from a handful of branded products, primarily the epinephrine injector EpiPen.” The EpiPen is the only drug specifically mentioned by name. Indeed, in an October 18, 2016 report, Morningstar analyst Michael Zbinovec wrote that “Mylan’s specialty drug franchise is essentially comprised entirely of EpiPen.”<sup>9</sup>

53. EpiPen sales were also critically important to Mylan’s quarterly earnings results and Mylan’s ability to meet analyst expectations. For example, in a report dated February 11 2016, BTIG analyst Timothy Chiang wrote that Mylan was “in need of EpiPen after weak Q4,” to make up for a weaker than expected fourth quarter in 2015.<sup>10</sup> A few quarters later, when the Company beat expectations, analysts attributed the success to the EpiPen. For instance, in an August 9, 2016 report, Morgan Stanley analyst David Risinger noted that “Epipen drove EPS slightly above” expectations.<sup>11</sup> Similarly, in an August 10, 2016 report titled “Epipen takes the driver’s seat,” Barclays analyst Douglas D. Tsao concurred that “Epipen was clearly the big driver of 2Q results.”<sup>12</sup>

54. EpiPen sales also drove analysts’ ratings and evaluations of Mylan’s financial prospects. Numerous analysts equated risks to the EpiPen business with risks to their evaluations

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<sup>8</sup> Chris Schott, Dana Flanders & Aditi Singhania, *Mylan NV: Updating Estimates for Epipen; Remain Cautious In NT But Valuation Offers Compelling LT Entry Point*, J.P.Morgan (Oct. 4, 2016).

<sup>9</sup> Michael Waterhouse & Damien Conover, *Mylan’s EpiPen pricing blowback doesn’t dramatically alter the company’s significant challenges*, Morningstar (Oct. 18, 2016); and Michael Zbinovec, *Mylan is digesting Meda while facing EpiPen headline risk*, Morningstar (Oct. 18, 2016).

<sup>10</sup> Timothy Chiang & Ben Shim, *Mylan N.V.: In Need of Epipen After Weak Q4; Net Model w/ Meda Suggests Much Needed Accretion is Possible; Buy*, BTIG (Feb. 11, 2016).

<sup>11</sup> David Risinger, et al., *Mylan Inc.: Epipen drove EPS slightly above; guidance unchanged despite early deal closings*, Morgan Stanley (Aug. 9, 2016).

<sup>12</sup> Douglas D. Tsao & Morgan Williams, *Mylan Inc.: Epipen takes the driver’s seat, Barclays* (Aug. 10, 2016) (Oct. 18, 2016).

of Mylan as a whole. For instance, JPMorgan analysts included “generic competition for Epipen” as one of three “[r]isks to the downside” for its overall rating of and price target for Mylan, in its reports on March 1, 2016, August 10, 2016, October 4, 2016, and October 10, 2016.<sup>13</sup> Morgan Stanley analysts also repeatedly included “FDA approval of pharmacist-substitutable generic Epipen” as the first risk listed in a section titled “Risks to Achieving Price Target,” including in a February 12, 2016 report and again in an August 9, 2016 report.<sup>14</sup> BTIG analysts similarly stated that the one of the three “key risks” to its evaluation of Mylan were “Epipen revenues not meeting estimates,” in a January 21, 2016 report and again in an August 29, 2016 report.<sup>15</sup>

55. During the Relevant Period, Mylan’s sales of EpiPen through Medicaid accounted for a very significant amount of Mylan’s total sales of the EpiPen. In an October 10, 2016 report, UBS analyst Marc Goodman estimated that “Medicaid spending on EpiPen is ~35% of [Mylan’s total] 2015 [EpiPen] sales.”<sup>16</sup>

56. As Mylan’s sales of EpiPen constituted a massive part of Mylan’s business, and as sales of EpiPen through Medicaid accounted for a very significant part of Mylan’s EpiPen

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<sup>13</sup> Chris Schott, et al., *MYL/TEVA: Positive Epipen News Supports EPS Upside for MYL*, J.P.Morgan (March 1, 2016); Chris Schott, et al., *Mylan NV: Solid Qtr Lead by Epipen; Long-Term Growth Trajectory Remains Intact*, J.P.Morgan (Aug. 10, 2016); Chris Schott, et al., *Mylan NV: Updating Estimates for Epipen; Remain Cautious in NT But Variation Offers Compelling LT Entry Point*, J.P.Morgan (Oct. 4, 2016); and Chris Schott, et al., *Mylan NV: Epipen Rebate Settlement and Updated Guidance A Positive*, J.P.Morgan (Oct. 10, 2016).

<sup>14</sup> David Risinger, et al., *Mylan: Epipen 4Q sales hurt by inventory workdown, not price adjustments as we hypothesized*, Morgan Stanley (Feb. 12, 2016); and David Risinger, et al., *Mylan Inc.: Epipen drove EPS slightly above; guidance unchanged despite early deal closings*, Morgan Stanley (Aug. 9, 2016).

<sup>15</sup> Timothy Chiang & Ben Shim, *Mylan N.V.: Upping Estimates to Reflect Higher Epipen Sales; Buy*, BTIG (Jan. 21, 2016); and Timothy Chiang, *Mylan N.V.: MYL to Launch Authorized Generic Version of Epipen*, BTIG (Aug. 29, 2016).

<sup>16</sup> Marc Goodman, *Mylan Inc.: We’re Still Constructive on MYL*, UBS (Oct. 10, 2016). This estimate relied on the October 5, 2016 letter to Senator Ron Wyden from CMS Acting Administrator Andrew M. Slavitt, which reported that total Medicaid spending on EpiPen from 2011 to 2015 was \$960 million, with \$253 million spent in 2014 and \$365 million in 2015.

sales, Mylan's classification of the EpiPen for the purposes of the MDRP was highly consequential to the Company.

**C. Legal Classifications of Drugs for the Purposes of the MDRP**

57. Medicaid is a public assistance program that provides healthcare coverage for those members of society who cannot afford healthcare. All states, the District of Columbia, and the U.S. territories have Medicaid programs designed to provide healthcare coverage for low income individuals. Jointly funded by the state and federal governments, Medicaid is the largest source of funding for medical and health-related services for Americans with low income. Medicaid accounts for 17% of all U.S. healthcare expenditures.

58. The MDRP, which was created as part of the Omnibus Budget Reconciliation Act of 1990 (the "1990 Act"), requires a drug manufacturer to enter into, and have in effect, a rebate agreement with "CMS in order to receive state Medicaid coverage of the manufacturer's drugs. The rebate agreement imposes reporting and rebating requirements on the drug manufacturers.

59. Drug manufacturers must submit product and pricing data concerning their drugs to CMS via the Drug Data Reporting for Medicaid system. Manufacturers are then responsible for paying a rebate for their covered drugs that have been purchased and dispensed under state Medicaid plans. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the federal government to offset the overall cost of prescription drugs under the Medicaid Program.

60. The purpose of the MDRP is to ensure that pharmaceutical companies grant appropriate bulk-discounts to government purchases of prescription drugs that are commensurate

with the massive volume of these purchases. CMS, which is part of the HHS, administers Medicaid in partnership with state governments.

61. However, in creating the MDRP, lawmakers recognized that generic drugs, which generally face significant competition from competitors, are less “overpriced” than brand-name drugs, which are usually patented and unique. Whereas competition usually will bring down the prices of generic drugs to close to the cost to the manufacturers of producing those drugs, market forces will not similarly bring down the price of brand-name drugs, which are patented or otherwise face no direct competition. Accordingly, lawmakers required drug manufacturers that participate in MDRP to provide a greater rebate for patented drugs and drugs that otherwise face no competition than for generic drugs, which the government already buys at close-to-cost prices.

62. A new brand-name drug must be submitted to the FDA for approval under a New Drug Application (“NDA”). NDAs must contain extensive data gathered from animal studies and human clinical trials.

63. Generic drugs, on the other hand, are submitted to the FDA for approval under an Abbreviated New Drug Application (“ANDA”). ANDAs generally do not include data gathered from animal studies and human clinical trials, but contain data to scientifically demonstrate that the generic drug performs in the same manner as the brand-name drug.

64. Drug manufacturers are responsible for correctly classifying their drugs and paying the correct rebate amounts for their drugs under the MDRP. When submitting information to CMS, manufacturers classify their drugs as either single source (“S” drugs), innovator multiple source (“I” drugs), or non-innovator multiple source (“N” drugs). The classification of the drug dictates how the rebate owed is calculated for that drug under the MDRP.

65. The rule for classifying drugs under the MDRP, is simple and unambiguous: drugs that are approved under a NDA must be classified as either “S” or “I” drugs, while drugs that are not approved under a NDA (such as those approved under an ANDA) must be classified as “N” drugs.”<sup>17</sup>

66. An NDA is the application drug manufacturers use to obtain approval to market a new drug, which is generally subject to a patent, whereas an ANDA is the application generic drug manufacturers use to seek approval to market a generic version of a drug already introduced to the market after gaining approval under an original new drug application. Therefore, under the 1990 Act, all drugs that are approved under NDAs (which are generally patented brand-name drugs) must be classified as S or I drugs, whereas all drugs that are approved under ANDAs (which are generic drugs) are classified as N drugs.

67. The difference between an S and an I drug is the existence of therapeutic equivalents. A drug approved under a NDA that has no therapeutic equivalents is an S drug, whereas a drug approved under a NDA that has therapeutic equivalents is an I drug.

68. While under the 1990 Act, a drug marketer need only know whether or not a drug was approved for marketing under an NDA in order to classify that drug correctly for the purposes of rebates under the MDRP, a second unambiguous, bright line rule in the statutory language also makes classification simple: *in no event* can a drug that does not face competition from any therapeutically equivalent drug be classified as a generic or N drug; that is, if a drug is the only drug on the market that, according to the FDA, offers the therapeutic benefits that it

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<sup>17</sup> In the language of the statute, a single source drug or S drug is “a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration . . . .” 42 U.S.C. § 1396r-8 (k)(7). An innovator multiple source drug or I drug is “a multiple source drug [*i.e.*, a drug that has at least one other “therapeutically equivalent” drug] that was originally marketed under an original new drug application approved by the Food and Drug Administration. *Id.* A noninnovator multiple source drug or N drug is “a multiple source drug that is not an innovator multiple source drug [*i.e.*, is not a drug that was originally marketed under an original new drug application approved by the Food and Drug Administration].” *Id.*

does, that drug cannot be a generic or N drug. Under 42 C.F.R. § 447.509, as relevant for the purposes of this Complaint, for a drug to be classified as an N drug there must be “at least one other drug product which [...] [i]s rated as therapeutically equivalent (under the Food and Drug Administration’s most recent publication of ‘Approved Drug Products with Therapeutic Equivalence Evaluations’).” That is, under the 1990 Act, a drug has a therapeutic equivalent if such an equivalent is listed in the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the “Orange Book.” The Orange Book is not hard to find—it has been available in the FDA’s public reading room since 1990, and has been available on the FDA’s website, in searchable form, since at least 2007.<sup>18</sup>

69. On October 1, 2007, the first regulations promulgated pursuant to the 1990 Act, 42 C.F.R. § 447.500 *et seq.*, became effective (the “2007 Regulations”). These regulations largely adopted the statutory definitions of S, I, and N drugs, and for the purposes of this Complaint, made only one small change to the classification scheme detailed in the 1990 Act: S or I drugs include, in addition to all drugs approved under an NDA, drugs “approved under a biologics license application (“BLA”), product license application (“PLA”), establishment license application (“ELA”), or antibiotic drug application (“ADA”).”<sup>19</sup> These applications are used only for certain medical products, such as vaccines, antibiotics, certain antibodies, blood and blood by-products, and tissue and cellular products; these applications are not used for drugs for the treatment of anaphylaxis. Accordingly, under the 2007 Regulations, the bright line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP remained unchanged; the 2007 Regulations simply expanded the bright line rule by

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<sup>18</sup> The current version of the Orange Book may be found at <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>.

<sup>19</sup> 42 C.F.R. § 447.502 (2007)

making clear that in addition to all drugs approved under NDAs, all drugs approved under BLAs, PLAs, ELAs and ADA must also be classified as S or I drugs.

70. On at least two occasions since 2007, CMS has issued guidance regarding the proper classification of drugs under the MDRP. Given that the classification of drugs for the MDRP is extremely straightforward, in both instances, CMS's guidance constituted exactly one paragraph. On January 5, 2010, CMS informed drug companies in Manufacturer Release No. 80:

In general, those products that are approved under a New Drug Application (NDA) need to be reported to CMS as either single source (S) or innovator multiple source (I) and those products approved under an Abbreviated New Drug Application (ANDA) need to be reported to CMS as non-innovator multiple source (N).<sup>20</sup>

71. On September 12, 2014, CMS repeated the same guidance quoted above in Manufacturer Release No. 91:

In general, covered outpatient drugs that are approved under a new drug application (NDA) should be reported to CMS as either "S" or "I" drugs, while drugs approved under an abbreviated new drug application (ANDA) should be reported to CMS as "N" drugs.<sup>21</sup>

72. The "in general" language in the above-quoted paragraphs is superfluous. No exception to the bright line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP exists in the statutory language of the 1990 Act or in the 2007 Regulations.<sup>22</sup>

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<sup>20</sup> Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 80* at 3 (Jan. 5, 2010).

<sup>21</sup> Centers for Medicare and Medicaid Services, *Medicaid Drug Rebate Program Notice for Participating Drug Manufacturers, Release No. 91* at 3 (Sept. 12, 2014).

<sup>22</sup> Moreover, industry practice and the practice of CMS is to classify a drug delivery product filed under a new drug application as an S or I drug, even if any patents covering the substance delivered by the product have expired.

73. In February 2016, CMS published a Final Rule modifying slightly the definitions of S, I, and N drugs found in the 2007 Regulations (the “Final Rule”).<sup>23</sup> The Final Rule became effective April 1, 2016 (the “2016 Regulations”).<sup>24</sup> Under the 2016 Regulations, the basic bright line rule that all drugs approved under an NDA must be classified as S or I drugs for the purposes of the MDRP remains unchanged, but the 2016 Regulations introduced a bright line exception to the rule: an NDA need not be classified as an S or I drug if and only if, following the effective date of the 2016 Regulations (April 1, 2016), a drug marketer requests that CMS treat a drug approved under an NDA as if it were approved under an ANDA for the purposes of the MDRP, and CMS then expressly determines that a “narrow exception” applies to that drug and grants the drug manufacturer leave to classify the drug as an N drug.<sup>25</sup> Notably, certain classes of drugs are categorically excluded from this “narrow exception.” In guidance published alongside the Final Rule, CMS stated, “the narrow exception will not be considered applicable to drugs . . . that received patent protection or statutory exclusivity.”<sup>26</sup>

74. In summary, from the beginning of the MDRP in 1990 until April 1, 2016, applicable law and regulations required all drugs approved under an NDA to be classified as S or I drugs for the purposes of the MDRP. After April 1, 2016, applicable regulations require all drugs approved under an NDA to be classified as S or I drugs for the purposes of the MDRP, unless CMS finds after April 1, 2016 that a narrow exception applies, and a narrow exception

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<sup>23</sup> Final Rule, 81 Fed. Reg. 5170 (Feb. 1, 2016).

<sup>24</sup> 42 C.F.R. § 447.509 (2016).

<sup>25</sup> In the language of the 2016 Regulations, in the definitions of S and I drugs, “an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies.”

<sup>26</sup> 81 Fed. Reg. 5170, 5191 (Feb. 1, 2016). As explained *infra*, this “narrow exception” cannot apply to Mylan’s classifications during the Relevant Period because: (1) a request for the exception could only be made after the effective date of the 2016 Regulations; (2) to date Mylan has not requested that this “narrow exception” apply to the EpiPen; and (3) in any event, the exception cannot apply to the EpiPen because the EpiPen has “received patent protection.”

will never apply to drugs that have received patent protection. Moreover, at no point have applicable laws or regulations permitted a drug that does not face competition from any therapeutically equivalent drug to be classified as a generic or N drug.

75. The difference in rebate amounts owed for generic and non-generic drugs is significant. In general, under current regulations, drug manufacturers must pay CMS a rebate of 23.1% of the average manufacturer price of patented drug classified as an S or I drug, yet the manufacturer need pay a rebate of only 13% of the average manufacturer price of a generic or N drug. A drug manufacturer reaps a substantial financial benefit if it classifies a drug as a generic or N drug for the purposes of the MDRP. Indeed, as explained below, Mylan was able to overcharge Medicaid by over \$700 million as a result of its misclassification of the EpiPen as a generic drug.

#### **D. History of Classifications of EpiPen for Purposes of the MDRP**

76. The emergency drug autoinjector pen was first invented in the mid-1970s at Survival Technology in Bethesda, Maryland by Sheldon Kaplan. Initially, his device was called the ComboPen, and was purchased by the military for soldiers to use to autoinject nerve agent antidote in the event of chemical warfare. Kaplan and others eventually recognized that the same autoinjection technology, covered by U.S. Patent No. 4031893, among others, could be used to deliver epinephrine to treat anaphylaxis, and developed the EpiPen for that purpose. In the late 1980s, Survival Technology submitted the EpiPen to the FDA for approval under an NDA, and on December 22, 1987, the FDA approved the NDA, Number 019430, and permitted the EpiPen to be marketed in the United States.

77. When the EpiPen first was reported to CMS for the purposes of the MDRP, the EpiPen was classified accurately as a non-generic S drug.<sup>27</sup> As explained above, under the 1990 Act, all drugs that are approved under NDAs must be classified as S or I drugs. The EpiPen was approved under an NDA, so Survival Technology had to classify it as an S or I drug. Survival Technology accurately classified the drug as an S drug because the drug had no FDA approved therapeutic equivalents (nor has it ever had any therapeutic equivalents).

78. In 1996, Survival Technology merged with Brunswick Biomedical to form Meridian Medical Technologies Inc. (“Meridian”), and in 1997, Dey Inc. (“Dey”), a subsidiary of Merck, acquired the exclusive right to market and distribute the EpiPen from Meridian.<sup>28</sup>

**E. Mylan Knowingly or Recklessly Misclassified the EpiPen for the Purposes of the MDRP Ever Since it Began Selling the EpiPen to Medicaid.**

79. In 1997, Meridian sold the exclusive rights to market and distribute the EpiPen to Dey, a subsidiary of Merck. Mylan acquired the rights to market and distribute the EpiPen from Merck in 2007. From October 2, 2007 to the present, the responsibility of correctly classifying the EpiPen for the purposes of the MDRP shifted to Mylan.

80. As the following facts make clear, from 2007 to the present, Mylan knowingly or recklessly misclassified the EpiPen as a generic N drug for the purposes of the MDRP.

**1. Proper Classification of the EpiPen as a Brand-Name Drug Is Straightforward under Applicable Laws and Regulations**

81. While Mylan is a massive multinational corporation valued at billions of dollars, and had an army of sophisticated lawyers available to provide advice in 2007 and thereafter on

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<sup>27</sup> Letter from Andrew Slavitt, C.M.S. Acting Administrator, to Ron Wyden, U.S. Senator, at 2 (Oct. 5, 2016).

<sup>28</sup> Meridian was acquired in January 2003 by King Pharmaceuticals (“King”), which was then acquired by Pfizer in 2010; accordingly, Meridian is now a subsidiary of Pfizer. Pfizer, through Meridian, currently owns the non-expired patents on the EpiPen and currently manufactures the EpiPen for Viatris, while Viatris has exclusive rights to sell and market the EpiPen.

the proper classification of the EpiPen, the proper classification of the EpiPen required no sophisticated legal expertise at all.

82. Mylan’s classification of the EpiPen as a generic N drug for the purposes of the MDRP was manifestly contrary to the 1990 Act and to the 2007 Regulations, both of which clearly required that all drugs that are approved under NDAs must be classified as S or I drugs. The question whether a drug was approved under an NDA is not a puzzle—if Mylan somehow did not gather from Dey the application type under which the EpiPen was approved, Mylan easily could have looked up the application type through the FDA, including through a simple online search.<sup>29</sup> As the EpiPen was approved under an NDA, the 1990 Act and the 2007 Regulations required Mylan to classify the EpiPen as an S or I drug.

83. While there was no ambiguity in this classification requirement, the 1990 Act and the 2007 Regulations also make clear that in no event may a drug that has no FDA-approved therapeutic equivalent be classified as an N drug. Again, whether a drug has an FDA-approved therapeutic equivalent is not a puzzle—under the 1990 Act a drug has a therapeutic equivalent if such an equivalent is listed in the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations.” The text of the 2007 Regulations themselves included a government website address drug manufacturers could visit to determine whether a drug had a therapeutic equivalent:

For the list of drug products rated as therapeutically equivalent, see the FDA’s most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations” which is available at <http://www.fda.gov/cder/orange/default.htm> or can be viewed at the FDA’s Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A-30, Rockville, MD 20857.

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<sup>29</sup> The application type appears at U.S. Food and Drug Administration, Drugs@FDA: FDA Approved Drug Products, *available at* <https://www.accessdata.fda.gov/scripts/cder/daf/> process&ApplNo=019430 (last visited Feb 10, 2020).

84. The EpiPen has never had an FDA-approved therapeutic equivalent. In fact, in recent years Mylan filed a citizen's petition with the FDA in which it argued that the epinephrine autoinjector from a competitor, Teva Pharmaceutical Industries Ltd. ("Teva"), was not therapeutically equivalent to the EpiPen. Mylan argued that Teva's autoinjector lacked certain patented features of the EpiPen and required the user to remove two caps in order to use the device correctly, whereas the EpiPen required the user to remove only one cap before use. Mylan submitted data from studies that, according to Mylan, indicated that users accustomed to use of the EpiPen would not reliably use Teva's autoinjector correctly in an emergency due to these differences and others in the designs of the injectors. Mylan expressly argued that a difference in the design of an injector can create a therapeutic advantage for one product over another, even if the two products are both injectors of the same drug. The FDA ultimately determined that Teva's epinephrine autoinjector was not therapeutically equivalent to the EpiPen.

85. As the EpiPen has never had an FDA-approved therapeutic equivalent, the EpiPen cannot be classified as a generic N drug under the 1990 Act and the 2007 Regulations. For this additional reason, Mylan's classification of the EpiPen as a generic N drug was manifestly contrary to the 1990 Act and the 2007 Regulations.

**2. Mylan and Defendants Bresch, Malik, and Parks Repeatedly Affirmed in SEC Filings the Simple Rule that Drugs Approved under an NDA Are Brand-Name Drugs for the Purposes of the MDRP**

86. Defendants Mylan, Bresch, Malik, Parks, and Nesta knew or recklessly disregarded that Mylan's classification of the EpiPen as a generic N drug was manifestly contrary to the 1990 Act and the 2007 Regulations. In Mylan's 10-K filings throughout the Relevant Period, Mylan admitted that:

The required rebate [under the MDRP] is currently 13% of the average manufacturer’s price for sales of Medicaid-reimbursed products marketed under NDAs, up from 11% for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs required manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer’s price or the difference between the average manufacturer’s price and the best price during a specific period.

87. In these SEC filings, Mylan, and Defendants Bresch, Malik, and Parks who signed them, made clear that they understood the MDRP to require drug companies to rebate products based entirely on whether those products were marketed under NDAs or under NDAs. As the EpiPen was marketed under an NDA, Mylan’s own SEC disclosures imply that Mylan was required to give Medicaid the greater rebate applicable to brand drugs (of approximately 23% of the average manufacturer’s price) for the EpiPen.

### **3. CMS Expressly Informed Mylan Prior to the Relevant Period that Mylan’s Classification of the EpiPen Was Incorrect**

88. CMS expressly told Mylan that its classification of the EpiPen as a generic N drug was incorrect. On March 12, 2009, following the release of a report prepared by the HHS Inspector General (“HHS IG”) titled “Accuracy of Drug Categorizations for Medicaid Rebates,” CMS staff requested that the HHS IG provide it with a list of the eight drugs the HHS IG had determined to be incorrectly classified for the purposes of the MDRP in the course of preparing the report. In response to this request, on March 16, 2009 the HHS IG provided CMS with the list of misclassified drugs, and that list included the EpiPen. Subsequently, CMS notified Mylan about the misclassification. As CMS Acting Administrator Andrew M. Slavitt stated in a letter to Senator Ron Wyden, “The Center for Medicaid and CHIP Services in CMS has, on multiple occasions, provided guidance to the industry and Mylan on the proper classification of drugs and

has expressly told Mylan that [the EpiPen] is incorrectly classified.”<sup>30</sup> As CMS itself was expressly informed by the HHS IG on March 16, 2009 that the EpiPen was misclassified for the purposes of the MDRP, on information and belief, CMS was not derelict in performing its duties and told Mylan that the EpiPen was misclassified for the purposes of the MDRP shortly after having that misclassification highlighted to it by the HHS IG, and well before the start of the Relevant Period.

**4. Since 2004, Four New Patents Covering the EpiPen Have Been Granted, and Mylan Has Vigorously Participated in the Enforcement of those Patents**

89. Events in the years following Mylan’s initial classification of the EpiPen as an N drug further demonstrate that its misclassification was knowing or, at a minimum, extremely reckless. Since 2004, Meridian has received four additional patents for features that were subsequently integrated into the EpiPen: U.S. Patent Numbers 7,449,012, 7,794,432, 8,048,035, and 8,870,827 (the “EpiPen Patents”). These four patents have a priority date (*i.e.*, the date used to establish the novelty and/or obviousness of a particular invention relative to prior art) of August 6, 2004, and all will expire in 2025. These patents substantially altered the product Mylan acquired from Dey. As Mylan spokeswoman Lauren Kashtan has stated: “As anyone who has used the product knows, the epinephrine autoinjector we have in the market today is substantially different than the one we acquired.”<sup>31</sup>

90. The issuance of the EpiPen Patents, and Mylan’s designation of these patents as covering the EpiPen, further show that Mylan was acting disingenuously in classifying the EpiPen in effect as a generic rather than as a brand drug for the purposes of the MDRP. Mylan’s

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<sup>30</sup> Letter from Andrew Slavitt, C.M.S. Acting Administrator, to Ron Wyden, U.S. Senator, at 2 (Oct. 5, 2016).

<sup>31</sup> Intelligent Investments, *Mylan: \$5 Billion Potential Liability from EpiPen Underpayment of CMS Rebates*, Seeking Alpha, at 6 (Feb. 6, 2017) (quoting statement made to NBC News).

disingenuousness is underscored by the fact that Mylan vigorously and repeatedly sought to enforce these patents by participating in multiple lawsuits challenging potential generic competitors to EpiPen.

91. In 2009, Meridian and Mylan filed a patent lawsuit (the “2009 Lawsuit”) against Teva, which was preparing to introduce an epinephrine auto-injector that would compete with EpiPen. The 2009 Lawsuit accused Teva of seeking to “manufacture and sell a generic version of . . . [the] highly successful EpiPen® Auto-Injector prior to the expiration of U.S. Patent Nos. 7,449,012 B2 (the “’012 patent”) and 7,794,432 B2 (the “’432 patent”), which expire on September 11, 2025.

92. The 2009 Lawsuit noted that Meridian was “the holder of approved New Drug Application No. 019-430, which has the proprietary name EpiPen® (epinephrine) Auto-Injector 0.3mg/0.3 mL and 0.15mg/0.3 mL (‘EpiPen® Autoinjector’).” It also noted that Meridian had “submitted information concerning the ’012 patent and ’432 patent for listing in the FDA’s [Orange Book] on July 17, 2009 and September 15, 2010, respectively.” The 2009 Lawsuit further claimed that Teva’s application to the FDA for its classification of its proposed product “constitute[d] an act of infringement” of the EpiPen Patents at issue.

93. A similar lawsuit was filed in 2010 against Sandoz, Inc. (“Sandoz”) (“2010 Lawsuit”). The 2010 Lawsuit challenged the proposed “manufacture and s[ale] [of] a generic version of Plaintiff Meridian’s highly successful EpiPen® Auto-Injector,” and asserted the same patents as the 2009 Lawsuit. Like the 2009 Lawsuit, the 2010 Lawsuit asserted that Sandoz’s application to the FDA for its proposed product “constitute[d] an act of infringement” of the EpiPen Patents at issue.

94. In 2011, yet again, Mylan, in concert with Meridian, asserted the EpiPen Patents, this time in a lawsuit (“2011 Lawsuit”) against Intelliject, Inc. (“Intelliject”). Like Teva and Sandoz before it, Intelliject sought to introduce a competitor to EpiPen. Like the 2009 and 2010 Lawsuits, Mylan, in concert with Meridian and King, asserted the EpiPen patents to prevent Intelliject from proceeding in marketing its product, and argued that Intelliject’s application to the FDA “constitute[d] an act of infringement” of the EpiPen Patents at issue.

#### **5. In 2014, the DOJ Issued a Subpoena to Mylan Regarding Mylan’s Misclassification of the EpiPen**

95. In November 2014, Mylan received a subpoena from the DOJ as part of the its investigation into “whether EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate Statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs.”<sup>32</sup> Accordingly, by November 2014 at the very latest, the government agency responsible for enforcing compliance with the MDRP, the DOJ, had put Mylan on notice that Mylan’s classification of the EpiPen for the purposes of the MDRP was potentially incorrect.

#### **6. Mylan Marketed the Epipen as a Brand-Name Drug**

96. Mylan’s classification of the EpiPen as a generic drug is also in obvious tension with Mylan’s treatment of the EpiPen as a brand-name drug for all purposes other than the classification of this drug under the MDRP. After acquiring the right to the EpiPen, Mylan embarked on a years-long marketing campaign with the express purpose of promoting the EpiPen as an irreplaceable, unequalled, life-saving brand-name drug. That campaign has resulted in the EpiPen brand being compared to “Kleenex” amongst doctors, according to a 2015

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<sup>32</sup> Mylan N. V., Quarterly Report (Form 10-Q) at 56-57 (Nov. 9, 2016).

Bloomberg article. Indeed, in August 2015, Defendant Bresch touted “the brand equity with EpiPen” as a reason not to worry about the prospect of impending generics.

97. Further, Mylan tacitly acknowledged that one of the reasons for the EpiPen’s skyrocketing prices is that the EpiPen is a brand-name drug, and not a generic drug. Specifically, in December 2016, in the wake of controversy over EpiPen’s rising prices, Mylan introduced an “authorized generic” to the EpiPen priced at \$300, less than half the EpiPen’s list price. Such a measure would not have been needed were the EpiPen truly a generic drug, as Mylan claimed it to be in classifying the EpiPen as a generic N drug for the purposes of the MDRP.

98. Mylan wanted to have it both ways—it wanted to be able to charge the high prices commensurate with brand-name drugs, while reimbursing the government as little as possible under a classification intended to account for the lower profit margins associated with generic drugs. For years, Mylan succeeded in doing so.

#### **F. Mylan Knowingly or Recklessly Misled Plaintiffs and Other Investors Concerning its Misclassification of the EpiPen**

99. Throughout the Relevant Period, Mylan misled Plaintiffs and other investors about its misclassification of the EpiPen. In its annual and quarterly filings with the SEC, Mylan repeatedly and intentionally and/or recklessly led investors to believe that the classification of its drugs for the purposes of the MDRP was “complex and often involve[d] subjective decisions,” and was subject to “risk of errors and differing interpretations.” Moreover, Mylan repeatedly stated that there could be “ambiguity with regard to how to properly calculate . . . payments to Medicaid.” These statements failed to disclose the true situation Mylan faced with respect to its classification of the EpiPen, namely that Mylan’s classification of the EpiPen was blatantly incorrect under applicable law and regulations. The classification of the EpiPen was not complex and did not involve subjective decisions—as explained above, the classification was simple and

straightforward and turned simply on whether the drug at issue had been approved under an NDA (a yes or no matter that can be determined by looking on a government website), and whether the drug had therapeutic equivalents (also a yes or no matter that can be determined by looking on a government website). And the classification was not subject to a “risk of error”—that risk of error had materialized, as Defendants knew or were reckless in not knowing that the EpiPen was incorrectly classified. Likewise, the classification was not subject to “differing interpretations”—looking on the FDA website to check whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise.

100. These and Defendants’ numerous other misleading statements regarding its misclassification of the EpiPen are detailed herein.

**G. Mylan Knowingly Misled the Public by Implying Mylan Was Not Being Investigated for its EpiPen Classification when in Fact it Was**

101. Separately and independently, Mylan misled investors regarding whether a government authority had taken a position contrary to positions Mylan had taken regarding its classification of the EpiPen, and whether Mylan was being investigated for its EpiPen classification.

102. Throughout the Relevant Period in its quarterly and annual filings, Mylan stated that “should there be ambiguity with regard to how to properly calculate and report payments—and even in the absence of any such ambiguity—a governmental authority may take a position contrary to a position we have taken...” These statements were misleading from the start of the Relevant Period because, as explained above, prior to the Relevant Period, CMS had informed Mylan that its classification of the EpiPen was incorrect. Accordingly, there was not merely a possibility that a government agency might take a position contrary to Mylan’s regarding its

classification of the EpiPen—rather, a government agency had already taken a contrary position on that subject and had conveyed its contrary position to Mylan.

103. Moreover, on and after November 2014, Mylan’s statements that a government agency “may take a position contrary to a position we have taken” became doubly misleading because as of that date, the DOJ had already commenced an investigation relating to Mylan’s misclassification of the EpiPen. That is, by November 2014, the DOJ had indicated to Mylan that it had taken a position contrary to Mylan’s with respect to Mylan’s classification of the EpiPen, namely, that there was a substantial likelihood that Mylan had misclassified the EpiPen.

104. Mylan also misled investors concerning whether it was being investigated for its EpiPen classification. In the beginning of the Relevant Period, and in particular from February 2016 until November 2016, Mylan stated in its annual and quarterly SEC filings that “[a]ny failure to comply with [its payment obligations related to Mylan’s participation in Medicaid] could subject us to investigation. . . .” In stating that Mylan was subject to a risk of investigation for a failure to comply with its Medicaid payment obligations, including a failure to comply with its obligation to classify the EpiPen correctly for the purposes of the MDRP, without also disclosing that that risk already had materialized when the DOJ commenced an investigation into Mylan’s classification of the EpiPen, Mylan misled investors to believe that no such investigation was underway when in fact it was.

105. These and Mylan’s numerous other misleading statements regarding whether a governmental authority had taken a position contrary to its own regarding its classification of the EpiPen and regarding the existence of an investigation into Mylan’s classification are detailed in herein.

**H. Mylan’s Misclassification of the EpiPen and the Significance of the Misclassification Were Revealed Starting in September 2016**

106. Starting in September 2016, the truth about Mylan’s misclassification of the EpiPen for the purposes of the MDRP, and the significance of that misclassification for Mylan’s finances, was revealed to the market over a series of months. Some of these revelations are as follows.

**1. A Bipartisan Group of U.S. Senators Requested that the DOJ Investigate Mylan’s Classification of the EpiPen**

107. In a September 2016 letter, Senators Richard Blumenthal (D-Conn), Chuck Grassley (R-Iowa), and Amy Klobuchar (D-Minn), called on Attorney General Loretta Lynch to investigate Mylan’s classification of the EpiPen for the purposes of the MDRP. The letter noted that the EpiPen had not faced any FDA-approved competitors and that Mylan had actively prevented other drug marketers from introducing competing products; the letter concluded that the EpiPen was an “innovator drug” subject to the higher rebate under the MDRP. The letter stated that the facts “suggest that Mylan may have knowingly misclassified EpiPens, potentially in violation of the False Claims Act and other statutes.”

**2. Mylan Agreed to Pay a \$465 Million Settlement with the DOJ over its Misclassification of the EpiPen**

108. On October 7, 2016, Mylan announced in a press release that it had agreed to the terms of a \$465 million settlement with the DOJ and other government agencies “that w[ould] resolve questions that ha[d] been raised about the classification of . . . EpiPen Auto-Injector for purposes of the Medicaid Drug Rebate Program.” The press release explained that “the question in the underlying matter was whether EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs.” The press

release further stated that the settlement terms would resolve claims over “whether the product should have been classified as an innovator drug for CMS purposes and subject to a higher rebate formula.”

109. According to numerous press reports, the settlement terms also required Mylan to pay a higher rebate rate for EpiPen to Medicaid starting on April 1, 2017.

110. Following Mylan’s press release, numerous members of Congress criticized the purported DOJ settlement with Mylan for being excessively lenient. For example, on October 21, 2016, Senator Elizabeth Warren called the announced settlement “shamefully weak” and “shockingly soft.” According to Senator Warren, the announced settlement size was too small, and may have “rewarded” Mylan by allowing it to keep an additional \$65 million that it had made by “defrauding Medicare and Medicaid.” Senator Warren determined that Mylan has underpaid at least \$530 million in Medicaid rebates, and financial analysts have determined that Mylan’s underpayments were even greater.<sup>33</sup> Senator Richard Blumenthal of Connecticut similarly called on the Justice Department to reject the announced settlement.

111. On August 17, 2017, Mylan finalized an agreement with the DOJ to pay \$465 million to settle the government’s claims that Mylan misclassified the EpiPen to overcharge Medicaid by up to \$1.27 billion. Mylan announced this agreement in a press release issued the same day.

112. In the press release, Mylan effectively admitted that the EpiPen was misclassified by agreeing to reclassify the EpiPen as a brand-name “innovator” drug. The press release stated, “Mylan will reclassify EpiPen Auto-Injector for purposes of the Medicaid Drug Rebate Program and pay the rebate applicable to innovator products effective as of April 1, 2017.”

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<sup>33</sup> According to Evercore ISI senior analyst Umer Raffat, Mylan may have shortchanged Medicaid by \$707 million over the past five years.

**3. The SEC Opened an Investigation into Mylan Regarding its Classification of the EpiPen in October 2016**

113. The same day that Mylan announced its purported settlement with the DOJ, October 7, 2016, Mylan received “a document request from the Division of Enforcement at the SEC seeking communications with the CMS and documents concerning Mylan products sold and related to the Medicaid Drug Rebate Program, and any related complaints.”

114. Mylan did not disclose this SEC document request until a month later, in its Form 10-Q filed with the SEC on November 9, 2016

**II. Mylan Misled Investors by Failing to Disclose that it Was Engaged in Anticompetitive Conduct to Allow it to Inflate the Price of EpiPen**

115. Beyond Mylan’s overcharging Medicaid for over a decade for its purchases of the EpiPen, Mylan engaged in anticompetitive conduct during the Relevant Period in an attempt to hinder competition against the EpiPen. Among other conduct, Mylan offered unusually large rebates (30% and higher) to third-party payors in the medical insurance market and expressly conditioned those rebates on the payors’ dealing exclusively with Mylan.

116. Mylan misled investors by failing to disclose this anticompetitive conduct and the risk this conduct created that Mylan ultimately would be investigated for such conduct. When this conduct was revealed and when the risk of scrutiny of the Company’s practices materialized, Mylan’s stock dropped precipitously, injuring Plaintiffs.

**A. The Market for Epinephrine Autoinjectors**

117. Mylan has monopoly power in the market for epinephrine autoinjectors. Since Mylan acquired EpiPen, the product has accounted for more than 90% of the U.S. market for these devices. Mylan’s monopoly power allows it to raise prices without losing sales. As noted

above, Mylan has increased the price for EpiPen more than 500% since it acquired the rights to the device.

118. The overwhelming majority of patients in the U.S. who purchase epinephrine autoinjectors do so using their insurance coverage for prescription drugs.

### **1. Pharmacy Benefit Managers**

119. In the modern pharmaceutical industry, pharmacy benefit managers, or “PBMs,” play a significant role.

120. PBMs are third-party administrators of prescription drug programs for commercial healthcare plans, self-insured employer healthcare plans, federal government employee healthcare plans, and state government employee healthcare plans.

121. PBMs are extremely important to pharmaceutical companies because it is the PBMs that dictate whether a drug is covered by a patient’s insurance. PBMs do this by creating “formularies,” which list the prescription drugs included in the insurance plan and set the pricing tiers for those drugs. These formularies are usually tiered, such that drugs are placed on different levels according to the amount of co-payment patients are required to pay. As consumers prefer to pay as little as possible out of pocket for their medications, consumers are incentivized to select drugs on tiers with lower co-pays. If a drug is wholly excluded from a third-party payor’s formulary, the drug is not covered and is often too expensive for patients subject to that formulary to purchase without coverage. Prior to 2013, third party payors covered all available epinephrine autoinjectors (albeit at different tiers), but never excluded particular epinephrine autoinjectors from coverage entirely.

122. In addition to developing and maintaining the formulary, PBMs contract with pharmacies, negotiate discounts and rebates with drug manufacturers, and process and pay prescription drug claims.

123. The three largest PBMs – ExpressScripts, CVS Caremark, and OptumRx – control approximately of 80% of the PBM market in the U.S.

124. The overwhelming majority of epinephrine auto-injector prescriptions in the U.S. are filled by commercial third-party payors whose formulary is controlled by a PBM. Thus, a drug manufacturer's access to PBMs is critical if it wants to compete in the epinephrine autoinjector market.

**B. Mylan Excluded Sanofi from the Market for Epinephrine Autoinjectors by Offering Anticompetitive Rebates to Third-Party Payors Conditioned on Excluding Sanofi's Auvi-Q**

125. In January 2013, the drug company Sanofi introduced an epinephrine autoinjector, the Auvi-Q, to compete with the EpiPen. Sanofi sold the Auvi-Q for roughly the same price as that of the EpiPen. The Auvi-Q was a superior autoinjector to the EpiPen in several ways. The device was smaller than the EpiPen and was easier to carry in pockets or bags because its design was flatter than that of the EpiPen. The Auvi-Q was also easier to operate than EpiPen—the device issued audible voice instructions to permit first-time users or users panicking from an anaphylactic emergency to operate the device correctly without having to read instructions. The market welcomed this innovative device, and Auvi-Q sold successfully in the first few months following its release.

126. Mylan responded to this new competitive threat by excluding the Auvi-Q from the market. Shortly following the release of the Auvi-Q, Mylan began offering massive rebates to third-party payors on the express condition that the third-party payors not include the Auvi-Q in

their formularies among the epinephrine autoinjectors for which those payors would provide reimbursement. Mylan specifically targeted Auvi-Q by requiring third-party payors to exclude Auvi-Q, while allowing certain other epinephrine autoinjectors (deemed not to be a threat to EpiPen) to remain on some third-party payors' formularies. These rebates amounted to 30% or more of the price that Mylan otherwise would have offered. Mylan did not typically offer rebates for EpiPen, and when it did so, those rebates were generally low, usually below 10%. Mylan had no legitimate business reason to offer these unprecedented, deep rebates conditioned expressly on excluding the Auvi-Q from the market; they were offered to block that device from competing.

127. Mylan was able to pay for these massive rebates in at least two ways. *First*, Mylan increased the price of the EpiPen significantly (by more than 500% since 2007). *Second*, Mylan's savings from its misclassification of the EpiPen for the purposes of the MDRP helped the Company subsidize these rebates. Indeed, due to Mylan's price increases, the net, after-rebate, price of EpiPen actually rose after it began its exclusionary rebates. Mylan offered no rebates or very low rebates when it sold the EpiPen in 2012 for around \$200, but when Mylan began to offer a 30% rebate on the EpiPen and increased its price to around \$300 by 2014, the net price of EpiPen rose to \$210. For this and other reasons, Mylan's rebates did not have any procompetitive effects.

128. Because Sanofi did not have a large enough share of the epinephrine auto-injector market to offer comparable discounts to the PBMs, Mylan was able to defeat Sanofi from effectively competing with the EpiPen. Sanofi was unable to offer massive rebates on Auvi-Q in line with those offered by Mylan for EpiPen without offering rebates in excess of its revenues from Auvi-Q. Given Mylan's massive market share, the opportunity cost to third-party payors of

foregoing Mylan's rebates would have been very significant. As the Auvi-Q accounted for only around 10% of the market for epinephrine autoinjectors, Sanofi would have had to offer rebates far greater than Mylan's for each Auvi-Q Sanofi sold to a third-party payor in order to match the total value of Mylan's rebates that the payor would have to forego in order to buy the Auvi-Q. Indeed, Sanofi would have had to offer rebates far in excess of its revenues from Auvi-Q to match Mylan's rebates, given EpiPen's market share.

129. Mylan successfully blocked Sanofi from accessing a large portion of the epinephrine auto-injector market. In 2013, many of the largest third-party payors announced that Auvi-Q would not be covered in their formularies, and in 2014, more than half of the ten largest commercial third-party payors did not cover AuviQ in order to obtain Mylan's rebates. Mylan successfully blocked Auvi-Q from accessing nearly 50% of the U.S. market for epinephrine autoinjectors. In 2014, Mylan's anticompetitive rebates blocked Auvi-Q from about 45% of the individuals covered by commercial payors. In certain states in which third-party payors that did not cover Auvi-Q due to Mylan's exclusionary rebates were particularly pervasive, Sanofi's Auvi-Q was blocked from significantly more than 50% of the market.

130. The decisions of third-party payors not to cover Auvi-Q also led doctors to decline to prescribe Sanofi's product, which led to Mylan's effectively excluding the Auvi-Q from well over 50% of the national market for epinephrine autoinjectors. Doctors are generally familiar with which drugs are broadly covered by insurance, and when doctors know a particular drug is often not covered, or covered at an unfavorable tier, they often will decline to prescribe that drug to a patient.

131. Other pricing practices exacerbated the effect of Mylan's exclusionary rebates and further allowed Mylan to exclude Sanofi from the market. Around the time of Sanofi's release of

the Auvi-Q in 2013, Mylan started offering \$0 co-pay coupons for EpiPen, which allowed customers to purchase EpiPen without paying a co-pay to the pharmacy. Sanofi responded by also offering \$0 co-pay coupons. However, due to Mylan's rebates to commercial third-party payors, most such payors excluded Auvi-Q, and most of the payors that did not nevertheless offered Auvi-Q only at a less preferred coverage tier. As a result, the co-pay for Auvi-Q, when it was covered at all, was typically \$50 to \$75, while the co-pay for the EpiPen was only \$25. Accordingly, to compete with Mylan by offering \$0 co-pay coupons for Auvi-Q, Sanofi had to absorb two to three times more lost revenue that Mylan had to absorb in offering these co-pay coupons.

132. When Mylan's conditional rebates blocking Auvi-Q took effect around December 2013, within one month, Auvi-Q's U.S. commercial payor market share in the market for epinephrine autoinjectors dropped by nearly 50%, from about 13% to around 8%. This market share dropped to 7% by May 2014. By April 2014, Auvi-Q's national market share across all payors had slid from a maximum of 11% in mid-2013 to only 6%, while its market share in 2014 had been projected by Sanofi to exceed 20%. By October 2015, Auvi-Q's national market share was less than half of what Sanofi had projected.

133. By contrast, in Canada, where Sanofi branded and sold an epinephrine autoinjector called "Allerject" that was otherwise identical to the Auvi-Q, Sanofi's product competed well against the EpiPen. In Canada, Allerject and the EpiPen were treated the same on drug formularies due to government regulations, and the two devices were equally available for physicians to prescribe to consumers. Sales of Allerject in its first year on the market (in 2013) exceeded projections and accounted for 21% of the Canadian epinephrine autoinjector market. This market share rose to 25% by the end of 2014, and to 32% in 2015.

134. In the United States, a few third-party payors included Auvi-Q in the same coverage tier as the EpiPen. The Auvi-Q's market share for these payors exceeded expectations and reached as high as 20-25% by the end of 2013 and exceeded 30% in 2015. This success makes clear that the Auvi-Q could have succeeded and gained market share against the EpiPen had Mylan not excluded it from the market.

135. Ultimately, in October 2015, Sanofi decided not to relaunch Auvi-Q. Sanofi claims that Mylan's conduct substantially contributed to Sanofi's decision to forego its investment in Auvi-Q and give up its rights to the product. In April 2017, Sanofi sued Mylan for antitrust violations.<sup>34</sup>

136. In this way, in offering rebates in exchange for exclusive dealing, and at levels that made it impossible for Sanofi to compete, and through other conduct, Mylan used its monopoly power anticompetitively, in a way that violated Section 2 of the Sherman Antitrust Act, or at a minimum, put Mylan at severe risk of harmful regulatory scrutiny, including lawsuits, investigations and other governmental action.

### **III. Mylan's Reporting Obligations as a Public Company**

137. Under the federal securities laws and the regulations and guidance promulgated by the SEC pursuant to those laws, companies whose stock is publicly traded in the U.S. – such as Mylan – have important reporting and disclosure obligations.

138. Public companies are required to file with the SEC certain disclosure documents containing comprehensive information about their business operations and their financial

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<sup>34</sup> See *Sanofi-Aventis U.S. LLC v. Mylan Inc.*, No. 2:17-cv-02452 (April 24, 2017 D.N.J.). The case has been consolidated in multi-district litigation under *In re: EpiPen (Epinephrine Injection, USP) Mktg, Sales Practices and Antitrust Litigation*, No. 17-md-2785 (D. Kan.). On December 21, 2017, the District Court in Kansas denied Defendants' motion to dismiss antitrust claims brought in that action, including Sherman Antitrust Act Section 2 claims, based on the conduct alleged in this complaint. See *In re EpiPen ((Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. 2785, 2017 U.S. Dist. LEXIS 209710, at \*78 (D. Kan. Dec. 21, 2017).

condition. Investors rely on the accuracy and transparency of these disclosures when determining whether to invest.

139. As a publicly traded corporation with significant operations in the U.S., Mylan is required to prepare its financial statements in accordance with United States Generally Accepted Accounting Principles (“U.S. GAAP”) in order for those financial statements not to be deemed misleading and inaccurate. U.S. GAAP is a set of rules and standards that are designed to ensure uniform financial reporting.

140. In addition to complying with U.S. GAAP, public companies are required to follow the standards developed by the SEC governing what information must be disclosed in financial statements and other public filings.

141. Public companies such as Mylan are required to maintain effective disclosure controls and procedures to ensure compliance with their SEC reporting obligations. An issuer’s top-ranking executives must be involving in creating and designing these controls, and also must personally guarantee their effectiveness.

142. The Committee of Sponsoring Organizations of the Treadway Commission’s Internal Control – Integrated Framework defines internal control as “a process, effected by an entity’s board of directors, management, and other personnel, designed to provide reasonable assurance regarding the achievement of objectives relating to operations, reporting and compliance.” With respect to the reporting and compliance aspects of this definition, the Integrated Framework specifically states that “[w]hen internal control is determined to be effective, senior management and the board of directors have reasonable assurance [that] . . . the organization prepares reports in conformity with applicable laws, rules and regulations, and standards established by legislators, regulators, and standard setters, . . . [and that] the

organization complies with applicable laws, rules and regulations.” *See The Committee of Sponsoring Organizations of the Treadway Commission’s Internal Control – Integrated Framework* § 3 (“Requirements for Effective Internal Control”).

143. Section 404 of SOX requires public companies to publish information in their annual reports concerning the scope and adequacy of their internal control structure and procedures for financial reporting, and also to assess the effectiveness of such internal controls and procedures. When management identifies a control deficiency, it cannot claim that its internal controls are effective if the control deficiency is deemed to be a material weakness.

144. Section 302 of SOX requires a public company’s chief executive officer and chief financial officer to provide certifications concerning their review of, and disclosure of information about, the company’s internal controls. Specifically, pursuant to rules promulgated by the SEC to implement Section 302 of SOX, the CEO and CFO are required to certify in each periodic report that:

- he or she has reviewed the report;
- based on his or her knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, no misleading with respect to the period covered by the report;
- based on his or her knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in the report;
- he or she and the other certifying officers:
  - are responsible for establishing and maintaining “disclosure controls and procedures” [i.e., controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports filed or submitted by it under the Exchange Act is recorded, processed,

summarized and reported, within the time periods specified in the SEC's rules and forms] for the issuer;

- have designed such disclosure controls and procedures to ensure that material information is made known to them, particularly during the period in which the periodic report is being prepared;
- have evaluated the effectiveness of the issuer's disclosure controls and procedures as of a date within 90 days prior to the filing date of the report; and
- have presented in the report their conclusions about the effectiveness of the disclosure controls and procedures based on the required evaluation as of that date;
- he or she and the other certifying officers have disclosed to the issuer's auditors and to the audit committee of the board of directors (or persons fulfilling the equivalent function):
  - all significant deficiencies in the design or operation of internal controls which could adversely affect the issuer's ability to record, process, summarize and report financial data and have identified for the issuer's auditors any material weaknesses in internal controls; and
  - any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal controls; and
- he or she and the other certifying officers have indicated in the report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

*Certification of Disclosure in Companies' Quarterly and Annual Reports*, Exchange Act Release 46427, § II.A (Sept. 9, 2002) (footnotes omitted).

145. Throughout the Relevant Period Mylan represented to investors that it was complying with these important public reporting obligations by timely disclosing truthful material facts about its business and maintaining effective internal controls. However, unbeknownst to the market, between 2014 and 2017, Defendants made material misrepresentations and failed to disclose material information that they had a duty to disclose, in order to artificially inflate the price of Mylan's common stock. Defendants did this by: (1)

misleading the investing public that Mylan was paying the correct rebate amount to Medicaid for the EpiPen when, in fact, Mylan was drastically underpaying Medicaid the rebates it owed on EpiPen sales funded by U.S. taxpayers; (2) lying to investors about their knowledge of the EpiPen misclassification; (3) cautioning the market that improper classification of the EpiPen could lead to regulatory scrutiny without informing investors that Mylan was already under investigation for misclassifying the EpiPen; (4) falsely asserting that the market for the EpiPen was very competitive without disclosing the anticompetitive conduct in which Mylan was engaging with respect to the EpiPen; and (5) incorrectly certifying that Mylan had effective disclosure controls and procedures when, in fact, such internal controls were virtually nonexistent.

**IV. Mylan Misled Investors by Failing to Disclose that it Was Engaged in Market Allocation and Price-Fixing of Generic Drugs**

146. During the Relevant Period, Mylan participated in a third massive, and separate series of frauds on investors—Mylan engaged in a wide-ranging scheme to allocate the market and fix the prices for virtually every generic drug that it marketed, including, but not limited to, Doxy DR, fenofibrate, clonidine-TTS Patch, tolterodine extended release, capecitabine, enalapril, valsartan HCTZ, albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, amiloride HCL/HCTZ, doxazosin mesylate, ketorolac, loperamide HCL, levothyroxine, methotrexate, nadolol, tizanidine, trifluoperazine HCL, budesonide DR, buspirone hydrochloride, cimetidine tablets, diclofenac potassium, diltiazem HCL, estradiol, fluoxetine HCL, flurbiprofen, fluvastatin sodium, haloperidol, ketoconazole, ketoprofen, nitrofurantoin MAC capsules, pentoxifylline, prazosin HCL, prochlorperazine, tamoxifen citrate, and tolmetin sodium, by agreeing with competitors to raise the prices substantially and simultaneously. Mylan misled investors about the competition it faced, the validity of its sales, and the risks the company faced by failing to

disclose that it was engaged in this anticompetitive conduct relating to these generic drugs. On May 10, 2019, the attorneys general of the 46 States filed the Connecticut Teva Action against Mylan and other generic drug companies for antitrust violations.<sup>35</sup> In the complaint, the 46 States tell the story, with great detail and relying on documentation, of how Mylan agreed to allocate the markets of numerous generic drugs with its competitors. The allegations in Section IV. of this Complaint are based in whole or in part on the complaint in the Connecticut Teva Action.

**A. For Years, Mylan and its Co-Conspirators Have Followed Anticompetitive Agreements Pursuant to Which Each Company Is Entitled to a “Fair Share” of the Market**

147. For many years, the generic pharmaceutical industry has operated pursuant to an understanding among generic manufacturers not to compete with each other and to instead settle for what these competitors refer to as “fair share.”

148. The overarching conspiracy among generic manufacturers—which ties together all of the agreements on individual drugs identified in this Complaint—is an agreed upon code that each competitor is entitled to its “fair share” of the market, whether that market is a particular generic drug, or a number of generic drugs. The term “fair share” is generally understood as an approximation of how much market share each competitor is entitled to, based on the number of competitors in the market, with a potential adjustment based on the timing of entry. Once a manufacturer has achieved its “fair share,” it is generally understood that the competitor will no longer compete for additional business. The common goal or purpose of this overarching agreement is to keep prices high, avoid price erosion and serve as the basis for further supra-competitive price increases.

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<sup>35</sup> See Complaint, *State of Connecticut v. Teva Pharmaceuticals*, No. 3:19-cv-00710-MPS (D. Conn. May 10, 2019), Dkt. No. 1.

149. This overarching agreement is widespread across the generic drug industry and is broader even than Mylan and the co-conspirators named in this Complaint. Mylan was among the most central participants in this overarching conspiracy. While this Complaint describes this conspiracy with reference at times to the sale of certain specific drugs, these specific drugs are merely examples of the operation of this overarching conspiracy, which affected all generic drugs Mylan sold.<sup>36</sup>

150. The exact contours of this “fair share” understanding, which has been in place for many years (and pre-dates any of the specific conduct detailed in this Complaint), has evolved over time during the numerous in-person meetings, telephonic communications, and other interactions between generic manufacturers about specific drugs. These business and social events occur with such great frequency, such that there was an almost constant ability for Mylan and its co-conspirators to meet in person and discuss their business plans. For example, between February 20, 2013 and December 20, 2013 (a 41-week period), there were at least forty-four (44) different tradeshows or customer conferences where Mylan and its coconspirators had the opportunity to meet in person. These in-person meetings gave Mylan and its co-conspirators the opportunity and cover to have these conversations, and reach these agreements, without fear of detection.

151. The “fair share” understanding among Mylan and its co-conspirators dictates that when two generic manufacturers enter the market at the same time, they generally expect that each competitor is entitled to approximately 50% of the market. When a third competitor enters, each competitor expects to obtain a 33% share; when a fourth competitor enters, each expects 25%; and so on, as additional competitors enter the market.

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<sup>36</sup> See Complaint, *State of Connecticut v. Teva Pharmaceuticals*, No. 3:19-cv-00710-MPS (D. Conn. May 10, 2019), Dkt. No. 1.

152. When a generic drug manufacturer is the first to enter a particular drug market on an exclusive basis, it is commonly understood that that manufacturer is entitled to a little more than its proportional share of the market. For example, when the pharmaceutical company, Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"), was about to enter the market for a drug in January 2013, the Vice President of Sales and Marketing explained during negotiations with his competitor that "he views it this way. If they [Dr. Reddy's] are first and others come out after, he deserves 60%. If he launches with others on day [one], he considers fair share 2-50%, 3-33%, 4-25%, etc."

153. Conversely, those generic manufacturers that enter later are typically entitled to a little less than their proportional share. One of the many examples of this occurred in March 2014, when Lupin Pharmaceuticals, Inc. ("Lupin") entered the market for the generic drug Niacin ER after Teva had previously been exclusive. At all times relevant to the Complaint, Nisha Patel ("Patel") worked as a Director of Strategic Customer Marketing and as a Director of National Accounts at Teva and David Berthold ("Berthold") worked as Vice President of Sales at Lupin. Patel of Teva and Berthold of Lupin, spoke directly by phone a number of times during this period, including three (3) calls on March 24, 2014. That same day, David Rekenthaler ("Rekenthaler"), Vice President of US Generics Sales at Teva, sent an internal e-mail to Patel. Here, Teva's expectation to maintain a 60% share in a two-player market, after being the first in that market, was consistent with the overarching conspiracy.

154. In fact, an employee at Taro Pharmaceuticals USA, Inc. ("Taro") went so far as to create a graphic representation of the industry understanding of "fair share," taking into account both the number of competitors and order of entry to estimate what its "fair share" should be in any given market.

155. Although these general parameters are well-known, there is no precise method for apportioning “fair share” because market share is ultimately determined by either winning or maintaining the business of various customers, which is inherently variable in a given year. The shared objective, however, is to attain a state of equilibrium, where no competitors are incentivized to compete for additional market share by eroding price.

156. Mylan’s scheme to minimize competition and allocate “fair share” was typically implemented as follows. First, Mylan and its co-conspirators allocated the market for an individual drug based on the number of competitors and the timing of their entry so that each competitor obtained an acceptable share of the market. Then, the competitors agreed on ways to avoid competing on price and, at times, significantly raised prices. This pattern was frequently followed even in the absence of direct communication between the competitors, demonstrating the universal code of conduct agreed to by Mylan and its co-conspirators.

157. This “fair share” understanding has been particularly effective when a new competitor enters the market—a time when, in a free-functioning, competitive market for generic drugs, prices would be expected to go down. In today’s generic drug markets, a new competitor will either approach or be approached by the existing competitors. Existing competitors will agree to “walk away” from a specific customer or customers by either refusing to bid or submitting a cover bid. The new competitor’s transition into the market is seamless; the new entrant is ceded market share and immediately charges a supra-competitive price. The competitors then continue this process of dividing up customers until the market reaches a new artificial equilibrium. This is referred to as a “stable” market.

158. “Fair share” principles also dictate how generic drug manufacturers respond when a competitor experiences supply issues. If the disruption is temporary, the existing competitors

will refrain from taking any action that might upset the market balance. By contrast, if the disruption is for a longer term, the competitors will divide up customers until each player achieves a revised “fair share” based on the number of players remaining in the market.

159. These rules about “fair share” apply equally to price increases. As long as everyone is playing fair, and the competitors believe that they have their “fair share,” the larger understanding dictates that they will not seek to compete or take advantage of a competitor’s price increase by bidding a lower price to take that business. Doing so is viewed as “punishing” a competitor for raising prices—which is against the “rules.” Indeed, rather than competing for customers in the face of a price increase, competitors often use this as an opportunity to follow with comparable price increases of their own.

160. When a generic manufacturer participates in this scheme, and prices stay high, this is viewed as “playing nice in the sandbox.” For example, in December 2014, Teva was approached by a large retail customer on behalf of Greenstone LLC (“Greenstone”), a wholly-owned subsidiary of Pfizer, that has at all relevant times operated as the generic drug division of Pfizer. The customer indicated that Greenstone was entering the market for Cabergoline and was seeking to target specific customers. The customer specifically requested that Teva give up a large customer to the new entrant, and indicated that “Greenstone has promised to play nice in the sandbox.” After discussing the matter internally, a Teva representative responded to the customer: “[t]ell Greenstone we are playing nice in the sandbox and we will let them have [the targeted customer.]”<sup>37</sup> Similarly, when a generic manufacturer is “playing nice in the sandbox,” it is generally referred to as a “responsible” or “rational” competitor.

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<sup>37</sup> See Complaint at 42, *State of Connecticut v. Teva Pharmaceuticals*, No. 3:19-cv-00710-MPS (D. Conn. May 10, 2019), Dkt. No. 1.

161. Adherence to the rules regarding “fair share” is critical in order to maintain high prices. Indeed, that is the primary purpose of the agreement. If even one competitor does not participate (and, thus behave in accordance with) the larger understanding, it can lead to unwanted competition and lower prices. In the relatively few instances where a competitor prioritizes gaining market share over the larger understanding of maintaining “fair share,” that competitor is viewed as “irresponsible,” and is spoken to by other competitors.

162. “Fair share,” “playing nice in the sandbox,” and similar terminology have become part of the industry lexicon, and thus, was part of the larger understanding between Mylan and its co-conspirators. Generic drug manufacturers actively and routinely monitor their fair share and that of their competitors, as well as discuss customer allocation amongst each other within the context of agreements on specific drugs.

163. The interdependence among generic manufacturers transcends product markets as these companies make decisions not only based on what impact their actions will have in a given product market, but also on how those actions will impact other product markets where the competitors overlap, and any future markets where they might eventually compete. During the Relevant Period, Mylan and other generic manufacturers often communicated about, and colluded on, multiple drugs at any given time. Indeed, it was not uncommon for generic manufacturers to communicate with each other about products that they did not sell. For example, on January 1, 2013—the day before a substantial Mylan price increase on a number of items—Kevin Green (“Green”), who—at that time—was the Director of National Accounts at Teva, spoke five (5) times with Defendant Nesta of Mylan. The next day, Green spoke with Armando Kellum (“Kellum”) who—at that time—was the Vice President of Contracting and Business Analytics at Sandoz. Kellum then sent an internal e-mail to the Sandoz team. Despite the fact

that Teva did not sell Levothyroxine, Green still conveyed to Sandoz that Mylan raised prices on that product.

164. Unlike their branded counterparts, generic drugs are commodities and generic manufacturers are constantly making decisions to enter new markets and leave existing markets. Often these decisions are made, at least in part, based on who the competitors are and how strong the relationship is between the two companies.

165. This interdependence between generic manufacturers is further demonstrated by the countless examples of companies sharing sensitive information with competitors as a matter of course. Mylan and its co-conspirators regularly forwarded bid packages from customers (Requests for Proposal) to each other. They also shared information among themselves regarding the terms of their contracts with customers, including pricing terms, price protection and rebates. Mylan and its co-conspirators used this information to negotiate prices on terms that are more favorable to them, often to the ultimate detriment of payors and consumers. For instance, in December 2013, Teva was negotiating new price increase language in its customers contracts, and wanted some comfort that its competitors had similar language. On December 23, 2013, Rekenthaler of Teva spoke with Defendant Nesta of Mylan three times, including a twelve (12) minute call, to confirm Mylan's position.

166. The scope of the anticompetitive activity is breathtaking. Currently the state attorneys general are investigating collusive activity with respect to over 300 generic drugs involving sixteen generic drug manufactures—virtually the entire generic drug industry.

**B. Anticompetitive Activity by Generic Drug Manufacturers Led to Widespread Increases in the Cost of Generic Drugs during the Relevant Period**

167. Mylan and its coconspirators embarked on one of the most egregious and damaging price-fixing conspiracies in the history of the United States. Mylan and its competitors sought to leverage the collusive nature of the industry to not only maintain their “fair share” of each generic drug market, but also to significantly raise prices on as many drugs as possible. In order to accomplish that objective, Mylan and its competitors with which it already had very profitable collusive relationships—referred to among the co-conspirators as “High Quality” competitors—decided to raise the prices in the markets for drugs the co-conspirators jointly dominated. Mylan had understandings with its highest quality competitors to lead and follow each other’s price increases, and did so with great frequency and success, resulting in many billions of dollars of harm to the national economy over a period of several years.

168. The prices for a large number of generic pharmaceutical drugs skyrocketed throughout the Relevant Period. Nearly 10% of generic drugs more than doubled in price between July 2013 and July 2014 alone, according to data from CMS. In the same time period, the price of more than 1,200 generic drugs increased by an average of 448%. A study by Fideres Partners LLP, released on December 22, 2016, identified 90 medicines the prices of which rose at least 250 percent between 2013 and 2016, and were increased by at least two drug companies around the same time, even though there was no obvious market reason for the increases. A January 2014 survey of 1,000 members of the National Community Pharmacists Association (“NCPA”) found that more than 75% of the pharmacists surveyed reported higher prices on more than 25 generic drugs, with the prices sometimes spiking by 600% to 2000% in some cases.

169. Mylan's CEO Defendant Heather Bresch informed investors about her inclination to raise prices right around the start of Mylan's recent price-fixing. These comments indicated that Defendant Bresch was focused on raising the prices of generic drugs, even though the market forces were pushing the prices of generic drugs down.

**C. Pricing Decisions at Mylan Were Reviewed and Approved by Mylan's Top Executives Who Were Fully Aware of Mylan's Market Allocation and Price-Fixing Activity**

170. Defendant Parks, by virtue of his responsibilities and activities as CFO, was privy to, and participated in, Mylan's fraudulent conduct described in this Complaint, including the market allocation and price-fixing schemes described in this Part.

171. According to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, a confidential witness ("CW1") reported that Defendant Parks, as CFO during the Relevant Period, knew of and approved all material drug pricing decisions made by the Company. CW1 started working at Mylan in 2010 as Director of Costing and later became Director of Production Planning before leaving Mylan in October 2015. CW1 worked in Mylan's Morgantown, West Virginia facility, which was at the time the largest pharmaceutical manufacturing plant in the world. CW1 was part of several groups that met regularly to assess costs. CW1 was responsible for cost accounting and overseeing plant manufacturing operations. CW1 also conducted cost analysis on certain products to assess the current market. In CW1's role as Director of Costing, CW1 worked directly with John Sheehan, who was CFO during the Relevant Period, and Defendant Anthony Mauro, who was Mylan's President prior to Defendant Malik. CW1 also attended company-wide meetings that were led by Defendant Bresch and concerned company initiatives.

172. CW1 stated that pricing decisions at Mylan occurred frequently and involved all of Mylan's top executives. “[Price] was always a topic.” CW1 stated in particular that the CEO and CFO of Mylan reviewed any price adjustments and had the last word on pricing decisions for Mylan's drugs. According to CW1, Defendant Bresch discussed price adjustments to Mylan's drugs frequently. “Especially if it was [pricing of] a specific product, everything went up through the top. We would have end of quarter and month meetings where we discussed pricing.” For example, “[w]hen we were looking at one product we were making for the government, an anthrax antibiotic, everyone, all the way to the president and CEO, discussed what price to sell it at.” CW1 understood the “anthrax antibiotic” in question to be doxycycline.

**D. Mylan Conspired with Other Drug Companies to Allocate the Market for Generic Drugs to Maintain Prices at Supracompetitive Levels**

173. When entering a generic drug market, Mylan and other generic drug companies routinely sought out their competitors in an effort to reach agreement to allocate market share, maintain high prices and/or avoid competing on price. These agreements had the effect of artificially maintaining high prices for a large number of generic drugs and creating an appearance of competition when in fact none existed.

**1. Doxy DR**

174. On December 14, 2016, the attorneys general of the 20 states filed a joint complaint against Mylan that was the product of a years-long investigation.<sup>38</sup> In the complaint, the 20 States detail the fruits of their investigation and tell the story, with great detail, of how

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<sup>38</sup> *Connecticut v. Aurobindo Pharma USA, Inc.*, No. 3:16-cv-02056, Complaint (Dkt. No. 1), at ¶ 55 (D. Conn. Dec. 14, 2016). On March 1, 2017, Connecticut filed an Amended Complaint that increased the number of states involved in the litigation from 20 to 40. The multistate group of plaintiff states now includes: Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington and Wisconsin.

Mylan agreed to allocate the market for Doxy DR with its competitors in order to maintain and increase the price of this drug at and to artificially high levels. The allegations in this subsection are based in whole or in part on that complaint.

175. Prior to 2013, Mylan was the only manufacturer of the generic drug Doxy DR. In 2013, Heritage Pharmaceuticals Inc. (“Heritage”) became interested in selling Doxy DR as well.

176. In mid-2013, Heritage executives began to reach out to Mylan executives in an effort to divide the market in order to refrain from competing with each other on prices.

177. In April 2013, Jason Malek (“Malek”), Vice President of Commercial Operations at Heritage and Heritage CEO, Jeffrey Glazer (“Glazer”), met with two executives of Heritage’s parent company, Emcure, and discussed their plans to enter the Doxy DR market and to coordinate how Heritage and Mylan could minimize competition between them. The group decided that Satish Mehta, the CEO of Emcure, would reach out to Defendant Malik, President and Executive Director of Mylan, to facilitate subsequent communications between Glazer and Malek and their Mylan counterparts.

178. On May 3, 2013, Jason Malek, Vice President of Commercial Operations at Heritage, requested that another Heritage employee set up a call between Malek and the Vice President of Sales at Mylan, but that Heritage employee replied that the Vice President of Sales at Mylan had little to do with National Accounts and recommended that Malek contact another individual at Mylan. Malek promptly connected with the Mylan employee through the website, LinkedIn. Over the next several weeks, Malek and the Mylan employee communicated by phone on multiple occasions.

179. Mylan and Heritage executives quickly became involved in the price fixing scheme. On May 7, 2013, Heritage’s President and CEO, Jeffrey Glazer, emailed Defendant

Malik in an effort to discuss dividing the market for doxycycline. Defendant Malik responded with a phone number where he could be reached in England. Malik and Glazer spoke the next day.

180. During this call, Glazer explained to Defendant Malik that Heritage had strong business relationships with two of Mylan's Doxy DR customers—a large wholesaler and a large retail pharmacy—and that Heritage intended to pursue Mylan's business at those two accounts. These two accounts represented approximately thirty-percent of the market.

181. Defendant Malik agreed to give up the two accounts to Heritage. Malik specifically cited Heritage's prior agreement to allow Mylan to enter the market for another drug without competition as a reason that Mylan would give up market share to Heritage in this instance. Malik told Glazer that he would let others at Mylan know of the plan.

182. During the course of these communications, Glazer and Defendant Malik agreed to allocate the market for Doxy DR between Heritage and Mylan, and agreed further that the two companies would refrain from competing against one another for customers in that market. The objective of this agreement was to avoid a price war that would reduce profitability for both companies.

183. In these communications, Mylan agreed to "walk away" from at least one large national wholesaler and one large pharmacy chain to allow Heritage to obtain the business from that wholesaler to increase Heritage's market share.

**(a) The Doxy DR Wholesale Account**

184. In June 2013, Malek of Heritage met a senior executive at the large national wholesaler at an Healthcare Distribution Management Association ("HDMA") conference in Orlando, Florida. Among other things, Malek discussed supplying the wholesaler with Doxy DR,

and very shortly thereafter, caused Heritage to submit a detailed product proposal, which Malek followed up by reiterating Heritage's keen interest in supplying the wholesaler with Doxy DR.

185. Concurrently with these discussions, Heritage and Mylan executives worked to allocate the Doxy DR market. For example, on June 11, 2013, a Mylan executive had a ten-minute phone conversation with a counterpart at Heritage about the Doxy DR market, and the Heritage executive left a voicemail with Malek about the conversation immediately thereafter. Shortly after that, Malek had a seven-minute conversation with the Heritage executive.

186. Similarly, on June 18, 2013, a senior manager at the wholesaler informed a Mylan executive by email about an unsolicited bid for Doxy DR by a new entrant, and asked Mylan to submit a bid to retain the contract by June 21, 2013, under the industry custom that an incumbent supplier has a right of first refusal by which it can beat a competitor's price to retain the business.

187. However, because Mylan had agreed to give up the wholesaler's account to Heritage, Mylan did not exercise its right of first refusal, and did not submit a bid.

188. On June 27, 2013, having received no bid from Mylan, the wholesaler entered into a distribution agreement with Heritage for Heritage to be the wholesaler's primary supplier of Doxy DR.

189. To date, Heritage has maintained the Doxy DR business with the wholesaler, and Mylan has not sought to compete for that business.

#### **(b) The Doxy DR Pharmacy Account**

190. A similar set of events played out with respect to the large retail pharmacy account. On July 8, 2013, Heritage submitted a proposal letter to the pharmacy to obtain its Doxy DR business, which the pharmacy initially rejected as being priced too high. Heritage emailed a revised bid on July 11, 2013, with a lower price.

191. Concurrently, both Heritage and parent Emcure kept Mylan updated on Heritage's efforts. Heritage particularly wanted to ensure Mylan was committed to the agreement and would cede the pharmacy account to Heritage. Thus, on July 18, 2013, Emcure CEO Mehta spoke to Defendant Malik to obtain Defendant Malik's assurance. The substance of their conversation was conveyed by Emcure personnel to Glazer by email shortly thereafter.

192. Glazer then emailed Defendant Malik to set up a call. Malik said he would call Glazer that evening, and indeed left him a voicemail when evening arrived. Glazer returned Malik's call fifteen minutes later and the two had a four-minute conversation. During the call, Glazer explained Heritage's strategy regarding the pharmacy account and Doxy DR in general to Malik, and the significance of how Mylan would respond to Heritage's bid for the pharmacy's business. After the call ended, Defendant Malik immediately spoke to other Mylan employees. Mylan would later react by ceding the business to Heritage.

193. On August 15, 2013, an executive at the pharmacy informed Mylan of an unsolicited bid for the Doxy DR business, and gave Mylan a short turnaround time to submit a counterbid. In accordance with Mylan's agreement with Heritage, Mylan submitted a noncompetitive counterbid that it knew would fail. Indeed, later that day, the pharmacy told Mylan the counterbid was not competitive enough and gave Mylan a second chance to further reduce its price. Mylan declined to do so, and, as a result, in September 2013, the pharmacy awarded its Doxy DR business to Heritage.

194. Through at least June 17, 2019, Heritage kept the business.

**(c) Further Efforts to Inflate Doxy DR Prices**

195. Even after Heritage obtained the foregoing two accounts, Heritage and Mylan continued to coordinate their efforts to prop up Doxy DR prices. On several occasions, Heritage

refrained from competing with Mylan for other customer accounts so as to avoid upsetting the two companies' arrangement. For example, in a November 25, 2013 email between Malek at Heritage and a contact at Mylan, the issue of one of Mylan's large accounts was discussed. Malek emailed Glazer the same day, and Glazer's response confirmed that the purpose of Heritage's agreement with Mylan was to maintain high prices in the market for Doxy DR. Glazer questioned whether Heritage should take any action that might disrupt that agreement. At the conclusion of the discussion, Heritage declined to pursue to large account so as to maintain to Doxy DR market-share balance between Heritage and Mylan.

196. In February 2014, Mayne Pharma (USA), Inc. ("Mayne") also entered the market for Doxy DR. Mayne approached Heritage even before it began selling the generic drug, in an attempt to obtain some of Heritage's market share. For example, on January 7, 2014, an employee at Mayne, spoke by phone with an employee at Heritage regarding obtaining some of Heritage's market share.

197. Shortly thereafter, Mayne made an unsolicited bid for the Doxy DR business of a large drug wholesaler. The bid prompted the wholesaler to approach Mylan, its supplier at the time of Doxy DR, to see whether Mylan would match Mayne's bid. At the same time, the wholesaler reached out to Heritage to see whether Heritage would also submit a bid for the wholesaler's Doxy DR business.

198. Internally at Heritage, Jason Malek noted that Heritage had sufficient supply of Doxy DR to meet the requirements of the wholesaler and to place a bid for those requirements, but Malek and others at Heritage worried that Mylan would perceive such a bid as an attack on Mylan's Doxy DR business in violation of the market allocation agreement between Heritage and Mylan, a violation that could result in Mylan's retaliating against Heritage. Accordingly, the

day after these internal discussions at Heritage took place, Heritage responded to the wholesaler that it declined to place a bid for the wholesaler's Doxy DR business. The reason Heritage gave to the customer to explain why Heritage could not submit a bid was that Heritage might not have enough supply to fulfill a contract with the wholesaler. Heritage's explanation, however, was a lie, because three days later, Heritage approached a different customer—a pharmacy chain—and asked if Heritage could bid for that company's Doxy DR business.

199. In late March 2014, Heritage learned that Mayne had made an unsolicited bid for Doxy DR to one of Heritage's large nationwide pharmacy accounts. On March 31, 2014, Heritage's Malek emailed Mayne, and over the following day and weeks, Mayne and Heritage communicated extensively via text message and email regarding Mayne's unsolicited bid. These communications were conveyed to Heritage CEO Jeff Glazer in early April 2014. This conflict was resolved when Mayne agreed to walk away from the large account.

200. In November 2014, Mayne made offers to the One Stop Program of McKesson Corporation ("McKesson"), a drug wholesaler, and Econdisc Contracting Solutions ("Econdisc"), a group purchasing organization that includes Express Scripts, Kroger, and Supervalu. Malek contacted personnel at Mayne to discuss the situation and raised the idea that Heritage and Mayne could allocate customers by having Mayne withdraw its offer to McKesson. Malek worked out an agreement with Mayne by November 25, 2014, which Glazer subsequently confirmed. Follow up communications occurred in December 2014 by text messaging and an in-person meeting at a conference of the American Society of Health-System Pharmacists held on December 9, 2014.

201. The agreement resulted in elimination of price competition and higher prices for doxycycline. When Econdisc put its business out for bid again in January 2015, Heritage

deliberately bid a higher price than Mayne, fulfilling its agreement to walk away from the Econdisc business. Likewise, when Heritage was requested to submit a bid by a large nationwide pharmacy chain in September 2015, it declined to do so after learning Mayne was the incumbent supplier.

202. Mylan and Heritage also continued to honor their agreement to allocate market share of Doxy DR and to avoid competing against each other. For example, on August 29, 2014, Heritage's Malek emailed a contact at Mylan and indicated that their agreement was still in effect.

## **2. Fenofibrate**

203. In 2013, Mylan conspired with Teva and Lupin to allocate the market for the generic drug Fenofibrate. Fenofibrate – also known by brand names such as Tricor – is a medication used to treat cholesterol conditions by lowering “bad” cholesterol and fats (such as LDL and triglycerides) and raising “good” cholesterol (HDL) in the blood.

204. As of the end of 2012, Teva and Lupin were the only major suppliers of generic Fenofibrate 48mg and 145mg tablets, with Teva having approximately 65% market share and Lupin having approximately 35% market share.

205. On February 27, 2013, K.G., a senior marketing executive at Teva, e-mailed multiple Teva colleagues to seek information on Mylan's potential entry into the market. In order to get this information, Green, who was Director of National Accounts at Teva, called Mylan's Vice President of National Accounts, Defendant James Nesta.

206. Defendant Nesta was, at all relevant times, a central player in Mylan's market allocation and price-fixing scheme. He was very senior at Mylan—he reported to Matthew Erick, who was at all relevant times President, North America for Mylan Pharmaceuticals. Matthew

Erick reported directly to Mylan's CEO, Defendant Bresch. Accordingly, Defendant Nesta was only one reporting level removed from the CEO, and was sufficiently senior at Mylan that his knowledge and actions may be imputed to the corporation.

207. Over the course of that day, Green of Teva and Defendant Nesta spoke at least four (4) different times. That same day, Green reported back to K.G. and other Teva colleagues what he had learned: Mylan planned to launch Fenofibrate 48mg and 145mg sometime around November 2013.

208. A few months later, however, Teva learned that Mylan was moving up its launch date for Fenofibrate. In advance of this launch, Teva, Lupin, and Mylan conspired to allocate the market for Fenofibrate. On May 8, 2013, Green e-mailed his colleagues at Teva. To assist in Teva's efforts to allocate the Fenofibrate market, Green asked a colleague at Teva for information about Teva's Fenofibrate business. This request for information was reiterated—and its purpose made clear—the following day when K.G. sent an internal e-mail stating that Mylan expected to launch Fenofibrate 48mg and 145mg tablets, and that he needed Teva's Fenofibrate sales and profitability information.

209. Up to this point, executives for Teva, Mylan and Lupin had all been in regular contact by phone. These calls include at least those listed below. On these calls, Teva, Mylan and Lupin executives shared information about Mylan's Fenofibrate launch and the plan to allocate market share to Mylan.

Date	Call Typ	Target Name	Direction	Contact Name	Duration
5/6/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:32
5/6/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:22:02
5/6/2013	Voice	Green, Kevin (Teva)	Outgoing	Berthold, David (Lupin)	0:01:00
5/7/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:10:31
5/7/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:06
5/7/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:00:18
5/7/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:11:12
5/7/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Berthold, David (Lupin)	0:02:53
5/8/2013	Voice	Nesta, Jim (Mylan)	Incoming	Berthold, David (Lupin)	0:00:05
5/8/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Berthold, David (Lupin)	0:08:55
5/8/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:20
5/8/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:00:05
5/8/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:05
5/8/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:03:46
5/9/2013	Voice	Green, Kevin (Teva)	Outgoing	Berthold, David (Lupin)	0:01:00
5/9/2013	Voice	Green, Kevin (Teva)	Incoming	Berthold, David (Lupin)	0:12:00
5/9/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:04:05

210. In one striking example of the coordination between the three companies, Defendant Nesta called Green of Teva at 2:42 PM on May 7 and they spoke for more than eleven (11) minutes. Immediately after hanging up the phone—at 2:54 PM—Nesta called David Berthold of Lupin and spoke for nearly three (3) minutes.

211. On May 10, 2013, K.G. received the Teva sales and profitability information he requested. After having the information for barely a half hour, and before there was even a formal price challenge by Mylan with any of Teva's customers, K.G. decided it would concede its Fenofibrate sales to Econdisc to Mylan. By conceding Econdisc to Mylan, Teva would walk away from its single biggest customer (in terms of gross profit) for the 48mg tablets and the third largest out of six customers (in terms of gross profit) for the 145mg tablets. The logic, of course, was to allocate a customer of sufficient size to Mylan so that Mylan would be comfortable with its "fair share" and not need to compete on price to acquire market share.

212. Teva executives immediately reached out to executives at Mylan and Lupin through a series of phone calls. These calls include at least those listed below. On these calls, executives of Teva, Mylan, and Lupin confirmed the market allocation scheme.

Date	Call Type	Target Name	Direction	Contact Name	Duration
5/10/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:28
5/10/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:10:46
5/10/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:02:19
5/10/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Patel, Nisha (Teva)	0:05:25
5/10/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:17
5/10/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:07:26
5/10/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:17:28

213. Teva made good on its agreement to concede Econdisc to Mylan. On May 15, 2013, Econdisc informed Teva that a new market entrant had submitted a competitive offer for Fenofibrate 48mg and 145mg tablets and asked Teva for a counteroffer to retain Econdisc's business. Less than an hour after receiving the notice of the price challenge, Green recommended conceding Econdisc. K.G. later agreed.

214. Following Teva's internal confirmation of the market allocation scheme, Teva executives spoke with executives at Mylan and Lupin numerous times. These calls include at least those listed below. On these calls, executives of Teva, Mylan, and Lupin confirmed that Teva was sticking to the market allocation scheme by conceding Econdisc to Mylan.

Date	Call Type	Target Name	Direction	Contact Name	Duration
5/16/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:36
5/16/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:02:07
5/16/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:00:07
5/16/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:03:12
5/16/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:00:04
5/16/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:05:29
5/16/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:34
5/17/2013	Voice	Berthold, David (Lupin)	Outgoing	Nesta, Jim (Mylan)	0:02:21
5/17/2013	Voice	Berthold, David (Lupin)	Incoming	Green, Kevin (Teva)	0:10:06
5/17/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:04
5/17/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:11:50
5/17/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:02:23
5/17/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:00:09
5/17/2013	Voice	Patel, Nisha (Teva)	Incoming	Berthold, David (Lupin)	0:00:21
5/17/2013	Voice	Patel, Nisha (Teva)	Outgoing	Berthold, David (Lupin)	0:11:12
5/17/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:04:25
5/17/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:05
5/17/2013	Text	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:00
5/17/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:16:02

### 3. Clonidine-TTS Patch

215. Clonidine-TTS Patch—also known by the brand name Catapres-TTS—is a medication in the form of a transdermal patch that is used to treat high blood pressure.

216. As of September 2011, Mylan and Teva were at rough parity in the market for generic Clonidine-TTS, with Mylan having approximately 48.4% market share and Teva having approximately 44.4% market share. At the end of 2011 and beginning of 2012, however, Teva began to take more than its “fair share.”

217. In November 2011, Teva took over Mylan’s business for Clonidine-TTS at Walgreens after Walgreens solicited Teva to provide a bid. Then, in late January 2012, Cardinal Health Inc. (“Cardinal”) solicited a bid from Teva for a one-time-buy to cover an alleged short-term supply shortage that Mylan was experiencing. A few days after Teva submitted its offer to

Cardinal for the one-time-buy, Cardinal asked Teva to become Cardinal's primary supplier for Clonidine-TTS. Believing that Cardinal's request was prompted by Mylan having supply issues, Teva accepted and took over the primary position at Cardinal for Clonidine-TTS.

218. On February 10, 2012, the move of Cardinal's business to Teva prompted K.G. of Teva to order his colleagues to get intelligence on the extent of Mylan's alleged supply issues. That same day, Rekenthaler of Teva called B.P., a senior national accounts executive at Mylan, to obtain the information and they spoke for six (6) minutes. Later that day, Rekenthaler reported back to his Teva colleagues. Rekenthaler was concerned that Mylan might retaliate against Teva for taking more than its "fair share" without consulting with Mylan. With the awards from Walgreens and Cardinal, Teva was projected to have between 65%-70% market share for Clonidine-TTS.

219. To gain back some market share, Mylan challenged Teva's Clonidine-TTS business at McKesson. Teva attempted to de-escalate the situation. Then, in April 2012, Mylan aggressively challenged Teva's Clonidine-TTS business at CVS to gain back market share and further signal its displeasure with Teva for taking the Cardinal business.

220. Teva heard Mylan's retaliatory message loud and clear. On May 4, 2012, just a few days after losing the CVS Clonidine-TTS business to Mylan, Teva was approached by Cardinal about a different drug, Doxazosin. At the time, Mylan was the primary supplier for Doxazosin at Cardinal. Cardinal representatives told Teva that Mylan was on backorder for one of the four Doxazosin dosage strengths until the end of June 2012, but Cardinal wanted to move the entire Doxazosin line to Teva. Teva declined to take this business.

221. On the morning of September 28, 2012, Defendant Nesta and Green of Teva spoke by phone at least twice, once for four (4) minutes and once for fourteen (14) minutes. On

those calls, Nesta informed Green of Mylan's impending temporary exit from the Clonidine-TTS market. As expected, later in the day on September 28, 2012, Teva began getting solicitations from Mylan customers, such as Wal-Mart and CVS, seeking a bid from Teva for Clonidine-TTS because Mylan had just issued a temporary discontinuation notice.

222. Mylan's exit from the Clonidine-TTS market presented an opportunity to raise prices and collusively reallocate the market at the inflated prices when Mylan fully reentered the market. For example, in April 2012, before Mylan had challenged Teva's Clonidine-TTS business at CVS, Teva's direct invoice price to CVS for the 0.1 mg, 0.2mg, and 0.3mg Clonidine-TTS was \$22.13, \$37.81, and \$54.41, respectively. Mylan's retaliation against Teva drove the prices to CVS down to below \$10.49, \$18.17, and \$26.51 for those dosages, respectively. Because of Mylan's exit from the market, however, when Teva took back the CVS business in October 2012, Teva was able to charge CVS a direct invoice price of \$33.28, \$56.08, and \$80.76, respectively.

223. Mylan and Teva maintained regular contact as former Mylan customers came to Teva because of Mylan's supply issues with Clonidine-TTS. For example, Teva submitted bids to CVS and Wal-Mart—which were ultimately accepted by those companies—on October 4, 2012 and October 5, 2012, respectively. In the days leading up to those bids, Teva and Mylan representatives had at least the following phone calls:

Date	Call Type	Target Name	Direction	Contact Name	Duration
10/1/2012	Voice	Rekenthaler, David (Teva)	Outgoing	B.P. (Mylan)	0:01:00
10/1/2012	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:00:10
10/1/2012	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:00:04
10/1/2012	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	0:00:06
10/1/2012	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	0:05:00
10/4/2012	Voice	Green, Kevin (Teva)	Incoming	Nesta, Jim (Mylan)	0:11:00

224. Teva and Mylan representatives continued to keep in contact going forward so that if Mylan reentered the Clonidine-TTS market, Mylan could regain market share without eroding price through competitive bidding. For example, on October 10, 2012, Green and Defendant Nesta spoke for ten (10) minutes. That same day, E.G. of Teva sent an e-mail to Teva national account managers and other senior representatives on this topic.

225. In or about February 2013, Mylan relaunched Clonidine-TTS and began seeking market share. In early March 2013 Mylan sought to secure the Clonidine-TTS business at Econdisc. Rather than competitively bid for the business, Teva's internal documents state that they chose to concede Econdisc back to Mylan. By April 2013, Teva also had conceded McKesson to Mylan.

226. In an internal e-mail dated February 28, 2013, Rekenthaler starkly admitted Teva's willingness to help Mylan regain market share without competition. Because Teva had been able to increase the price at CVS following Mylan's exit, Mylan gave a bid to CVS that was higher than Mylan's prior prices. CVS pushed Mylan to lower its bid in light of its prior prices but, confident that its brinkmanship would work because of Teva's cooperation, Mylan would not do so. Ultimately, CVS declined Mylan's bid because of Mylan's refusal to lower its bid in light of its prior pricing. Nonetheless, because Mylan's bid to CVS was not competitive—but rather an effort to allocate the market without eroding price—Teva was able to maintain artificially higher prices at CVS.

227. To carry out their scheme to allocate the Clonidine-TTS market without eroding price, representatives of Teva and Mylan remained in regular contact. In February and March 2013 alone, Teva and Mylan representatives called each other at least 33 different times and spoke for nearly 2 hours and 45 minutes.

228. By April 2013, having successfully allocated the market, Mylan and Teva were now conspiring to raise prices on Clonidine-TTS. On April 8, 2013, J.L., a marketing manager at Teva, reported internally to his Teva colleagues, including Rekenthaler, that Mylan had agreed to raise prices.

229. Green knew that Mylan would follow a price increase on Clonidine-TTS because earlier that day, Green had two phone calls with Nesta, with one lasting one (1) minute and the other lasting eight (8) minutes. In a follow up call the following day between Green and Nesta lasting eleven (11) minutes. Mylan and Teva reconfirmed their agreement that Mylan would follow a Teva price increase on Clonidine-TTS.

#### **4. Tolterodine Extended Release**

230. Tolterodine Extended Release (“Tolterodine ER”—also known by the brand name Detrol LA—is a medication used for the treatment of an overactive bladder.

231. Pfizer is the branded drug manufacturer for Detrol LA. To resolve patent infringement claims against Teva by Pfizer related to Detrol LA, Teva, and Pfizer entered into a settlement agreement under which Teva would distribute an authorized generic of Tolterodine ER. To resolve similar claims, Mylan entered into its own settlement agreement with Pfizer, which allowed Mylan to launch its generic version Tolterodine ER. On October 31, 2013, Mylan’s ANDA for Tolterodine ER was approved. Under their respective settlement agreements with Pfizer, this triggering event allowed Teva and Mylan to launch their respective generics on January 2, 2014.

232. Teva planned to launch on January 2, 2014. During the first half of December 2013, Teva was under the impression-based on conversations with potential customers—that Mylan was not in a position to launch until 30 to 60 days after Teva launched. Nonetheless, Teva

was considering how to allocate the market with Mylan when it did eventually launch. On December 3, 2013, J.K., a marketing executive at Teva, sent an e-mail to Rekenthaler, K.G., and several other Teva colleagues. To prepare offers and figure out the allocation of customers that would bring Teva its desired 50% to 60% market share, Teva executives were instructed to gather usage data from potential customers.

233. Through the first half of December 2013, as Teva was soliciting usage amounts from potential customers, customers were asking Teva to send in pricing offers before the launch. Teva resisted sending out those offers and instead did not plan to do so until the January 2, 2014 launch date. Teva's delay in putting together pricing for potential customers was part of a plan to drive up the amount it could charge for Tolterodine ER. Specifically, Teva expected that on January 7, 2014, Pfizer would raise the price of branded Detrol LA. This would allow Teva to peg its price to the now inflated price of the branded drug and thereby command a higher price for Tolterodine ER on the January 2, 2014 generic launch date.

234. At the end of the day on Friday December 20, 2013, T.C., an employee at Teva, learned from D.H., an employee at Cardinal, that Mylan intended to launch its Tolterodine ER on January 2, 2014. D.H. further provided T.C. with Mylan's pricing for two dosages.

235. T.C. informed her Teva colleagues of Mylan's plans. K.G. of Teva then worked over the weekend to turn this information into initial pricing for all of Teva's potential customers and then shared it internally. In a telling admission that Teva had no intention to bid competitively for all accounts, K.G. noted that the next step was to coordinate bids. The goal in coordinating bids was to ensure that both Mylan and Teva received their previously stated market share goals.

236. On Monday, December 23, 2013, David Rekenthaler, Vice President, Sales US Generics at Teva, Nisha Patel, Director Strategic Customer Marketing and Director of National Accounts at Teva, K.G., T.C., and several others at Teva had a telephone conference scheduled from 8:00 AM to 9:00 AM to discuss the Tolterodine ER launch strategy. Just minutes before the meeting was to start, Rekenthaler tried calling Defendant Nesta at Mylan. Nesta returned Rekenthaler's call at 8:15 AM, which was during Teva's scheduled Tolterodine ER phone conference. Rekenthaler nonetheless answered Nesta's call on his cell phone and the pair spoke for 1 minute, 26 seconds. Immediately after Teva's scheduled Tolterodine ER phone conference, Rekenthaler tried calling Defendant Nesta two more times. At 10:22 AM, Nesta returned Rekenthaler's calls and the pair spoke for an additional 12 minutes, 2 seconds. During these calls, Rekenthaler and Nesta exchanged the details about their offers to various customers, including the specific contractual language used in their offers.

237. For example, at 10:33 AM while Rekenthaler was still on the phone with Nesta, K.G. sent an e-mail to Rekenthaler and others asking about the appropriate contractual language to use in offers about the potential for price increases. Minutes after Rekenthaler finished his call with Nesta, he replied with the exact language, in quotes, that Mylan was using. Most importantly though, during these calls between Defendant Nesta and Rekenthaler, Teva and Mylan reached an agreement to allocate the Tolterodine ER market on launch day so that Teva and Mylan could reach their target share without eroding pricing.

238. At 12:12 PM on December 23, 2013, K.G. circulated a revised version of Teva's pricing plan for the Tolterodine ER launch. This new version incorporated Teva and Mylan's plan to allocate the market, including the submission of cover bids and abstention from bidding. Notably, the revised pricing plan included a chart identifying the major customers (and their

associated market share percentage) that Teva would receive to get close to its desired 60% market share while Mylan would get its desired 40% share.

239. Mylan and Defendant Nesta's acts of submitting cover bids to customers—bids that were meant to appear as genuine bids among competitors but were in fact intentionally uncompetitive—were deceptive acts in furtherance of their scheme to allocate the markets for generic drugs and ultimately to defraud investors, and these acts were independent of the Company's misleading statements.

240. In exchange for Mylan either submitting cover bids or abstaining from bidding on these customers, Teva reciprocated by submitting cover bids and/or refusing to submit bids to customers that Mylan targeted. This is demonstrated by the fact that Teva's newly revised pricing plan now included considerably higher direct invoice prices for major customers allocated to Mylan: namely Walgreens, Cigna, Humana, Optum RX Prime Therapeutics, and Kaiser.

241. In addition to submitting inflated bids for Walgreens, Cigna, Humana, Optum RX Prime Therapeutics, and Kaiser, Teva agreed to refrain from bidding for certain customers, such as Publix, Ahold, Hannaford, and PVA Health.

242. The following day, on December 24, 2013, Rekenthaler and Defendant Nesta had two more calls to confirm and refine Teva and Mylan's market allocation agreement. Those calls lasted for nine (9) minutes and eight (8) minutes, respectively.

## **5. Capecitabine**

243. Capacitabine, also known by the brand name Xeloda, is an anti-cancer chemotherapy drug used to treat a variety of cancers, including breast and colon cancer.

244. To resolve patent litigation, the brand manufacturer, Roche Pharmaceuticals entered into settlement agreements with various generic manufacturers—including Teva and Mylan—that would allow those generic manufacturers to sell generic Capecitabine after a certain period of time.

245. As early as January 2014, both Teva and Mylan were making plans for their eventual launch of Capecitabine. Part of this planning included the sharing of information so that they could allocate the market between them. For example, in a January 31, 2014 e-mail, J.P., a national accounts executive at Teva, informed K.G., Rekenthaler, and others at Teva that Mylan was courting a specific customer, Armada Health Care. Teva incorporated this data it received from Mylan into its own launch plan for Capecitabine.

246. On February 26, 2014, Defendant Nesta of Mylan called Rekenthaler of Teva and the two spoke for sixteen (16) minutes. Nesta informed Rekenthaler that Mylan would not be able to launch on time with Teva. Rekenthaler immediately reported this news internally at Teva.

247. In early March 2014, Teva launched as the exclusive generic Capecitabine manufacturer. Teva remained the exclusive generic Capecitabine manufacturer until Mylan entered in August 2014.

248. On August 4, 2014, Nesta and Rekenthaler spoke by phone three times. On these calls, Nesta informed Rekenthaler that Mylan would soon enter the Capecitabine market and the pair discussed how to allocate the market.

249. For example, at 12:46 PM that day, Nesta called Rekenthaler and they spoke for a little more than five (5) minutes. Immediately after hanging up the phone, Rekenthaler sent an e-mail to Maureen Cavanaugh, Senior Vice President, Commercial Officer, North America at Teva.

Cavanaugh responded that she would be in the office the next day and wanted to discuss it with Rekenthaler in person.

250. Less than an hour later, Rekenthaler sent another email, just to Patel, asking her to run a customer report and indicating that Mylan would seek the business of three particular companies. Mylan did seek the business for each of these three companies and Teva conceded each of them, pursuant to the agreement Rekenthaler had reached with Nesta.

251. On August 7, 2014, McKesson informed Teva that it received a bid for Capecitabine and gave Teva the opportunity to bid to retain the business. Patel then sent an email to K.G., Rekenthaler, and C.B. at Teva. K.G. questioned whether the competitive bid was coming from Mylan, and asked Rekenthaler whether he had any additional information. Rekenthaler did not want to put that information in writing, so he and others at Teva planned to discuss the bid.

252. The result was the market allocation scheme previously agreed to by Defendant Nesta and Rekenthaler on behalf of Mylan and Teva, respectively. The same day that Mylan put a bid in to McKesson—August 7, 2014—Nesta and Rekenthaler spoke by phone for nearly thirteen (13) minutes. On that call, Rekenthaler and Nesta discussed Mylan’s bid to McKesson and reconfirmed their market allocation scheme.

253. This market allocation scheme was highlighted in other e-mails as well. On August 10, 2014, C.B. e-mailed Rekenthaler, Patel, and K.G. about the plan with respect to Econdisc. Rekenthaler knew Mylan was targeting Econdisc, even though Econdisc had not contacted Teva, because he and Nesta had previously discussed it.

254. The next morning, at 8:30 AM on August 11, 2014, Rekenthaler alerted others at Teva that Mylan had received formal approval to market Capecitabine. Five minutes later,

Rekenthaler received a call from Nesta. After exchanging voicemails, the two spoke at 8:52 AM. The call lasted nearly six (6) minutes. Shortly after hanging up the phone, at approximately 9:02 AM, Rekenthaler e-mailed K.G., Patel and others at Teva.

255. In accordance with their market allocation scheme, Mylan targeted and Teva conceded the Capecitabine business at ABC, Econdisc, and McKesson/Rite-Aid.

256. Teva conceded other business as well, pursuant to the agreement. On August 14, 2014, for example, a smaller customer—Cigna—informed Teva that it received a bid for Capecitabine. On August 18, 2014, Rekenthaler called Nesta to discuss the market allocation scheme and Mylan’s bid to Cigna. The pair talked for thirteen (13) minutes. Teva declined to compete with Mylan’s bid in accordance with the market allocation scheme.

#### **6. Enalapril**

257. Enalapril Maleate (“Enalapril”), also known by the brand name Vasotec®, is a drug used in the treatment of high blood pressure and congestive heart failure. In 2009, the generic drug company Taro discontinued its sales of Enalapril under its own label and effectively exited the market. It continued supplying Enalapril thereafter only to certain government purchasers under the “TPLI” label. By mid-2013, the Enalapril market was shared by three players: Mylan with 60.3%, Wockhardt USA LLC (“Wockhardt”) with 27.5%, and Teva with 10.7%. Those three companies also coordinated a significant anticompetitive price increase for Enalapril in July 2013.

258. Shortly before the Teva’s and Wockhardt’s price increases, on or about July 12, 2013, Ara Aprahamian, the Vice President of Sales and Marketing at Taro, was considering whether to renew or adjust Taro’s price on Enalapril for its national contract (for government purchasers), which was slated to expire in September 2013.

259. In the midst of that coordinated price increase, however, Aprahamian was communicating with both Patel of Teva as well as M.C., a senior sales and marketing executive at Wockhardt, about Enalapril. As a result of those conversations, Taro's plans changed.

260. On July 17, 2013—the same day that Teva was taking steps to implement the price increase—Patel called Aprahamian and left a message. He returned the call and the two spoke for almost fourteen (14) minutes. Then, on July 19, 2013—the day that both Teva and Wockhardt's price increases for Enalapril became effective—Aprahamian called M.C. at Wockhardt on his office phone and left a message. He then immediately called M.C.'s cell phone, which M.C. answered. They spoke for nearly eleven (11) minutes.

261. On the morning of July 19, Aprahamian sent an internal e-mail to Taro colleagues signaling a change in plans. Aprahamian followed up with another e-mail shortly thereafter.

262. In the coming months, both Teva and Taro engaged in intensive analyses of how the market should look after Taro's re-launch so that each competitor would have its desired, or "fair share" of the market.

263. On July 31, 2013, for example, Patel provided her analysis of the drugs Teva should bid on in response to a request for bids from a major customer, which was largely based on whether Teva had reached its "fair share" targets. Patel authorized the submission of a bid for Enalapril. Prior to sending that e-mail, Patel had spoken to Aprahamian on July 30 (11 minute call) and July 31, 2013 (4 minute call). Based on the agreement between the two companies, and in accordance with the industry's "fair share" code of conduct, Taro understood that it would not take significant share from Teva upon its launch because Teva had a relatively low market share compared to others in the market.

264. In early December 2013, Taro was fully ready to re-enter the Enalapril market. On December 3, 2013, Aprahamian consulted twice by phone with Mylan's senior account executive, M.A., during conversations of two (2) and eleven (11) minutes.

265. On December 4, 2013, one customer that had recently switched from Wockhardt to Teva expressed an interest in moving its primary business to Taro for the 2.5mg, 5mg, 10mg, and 20mg strengths. At 4:30 PM that afternoon, Aprahamian instructed a colleague to prepare a price proposal for that customer for all four products.

266. Before sending the proposal to the customer, however, Aprahamian sought the input of his competitor, Teva. On December 5, 2013, he and Patel spoke by phone for nearly five (5) minutes.

267. Taro's fact sheet for the Enalapril re-launch generated on the day of Aprahamian's call with Teva showed a market share goal of 15% and pricing identical to Teva's and nearly identical to Wockhardt's and Mylan's.

268. Taro began submitting offers on Enalapril the following day, December 6, 2013. But even with the bidding process underway, Aprahamian made certain to communicate with Mylan's M.A. during a brief phone conversation that afternoon. This particular communication was important since Mylan was the market share leader and Taro was targeting more of Mylan's customers than those of other competitors.

269. Over the next ten days, the discussions between Taro and Mylan continued over how to allocate the Enalapril market. Aprahamian and M.A. talked for ten (10) minutes on December 11, and for seven (7) minutes on December 12.

270. Thereafter, and with the likely consent of Mylan, Aprahamian reported on an internal Sales and Marketing call on December 16, 2013, that Taro's prior target Enalapril market share goal of 15% had been raised to 20%.

271. Taro continued to gain market share from both Mylan and Wockhardt, and to coordinate with both. For example, in late December, Taro submitted a competitive offer to Morris & Dickson, a Wockhardt customer. This caused M.C. of Wockhardt to call Aprahamian on December 31, 2013 to discuss the situation. During the call, M.C. agreed that so long as Wockhardt was able to retain McKesson as a customer, it would concede Morris & Dickson to Taro. In an e-mail on January 2, 2014, S.K. of Wockhardt conveyed the details to his colleagues.

272. By May 2014 the market was stable, and market share for Enalapril was reasonably distributed among the companies. As Teva was considering whether to bid on specific drugs for an RFP sent out by a large wholesaler customer, Patel provided words of caution with regard to Enalapril in an email. The same day she sent that e-mail—May 14, 2014—Patel spoke to Aprahamian for more than four (4) minutes, and exchanged eight (8) text messages with him.

273. By June 2014, Taro had obtained 25% market share for Enalapril in a 4-player market. Mylan and Teva each had approximately a 28% market share.

## 7. **Valsartan HCTZ**

274. In September 2012, a senior sales executive at Sandoz ("S.E.") was concerned about her job security at Sandoz and sought to network with executives at competing companies in the hope of obtaining new employment. S.E. contacted Defendant Nesta because she was interested in potentially working at Mylan. S.E. obtained Nesta's phone number from a mutual contact and called to introduce herself. During that phone call, Nesta immediately started talking

about competitively-sensitive information. Although S.E. was surprised that Nesta was being so blatant, she did not stop him.

275. In the year that followed, between September 2012 and October 2013, S.E. and Defendant Nesta developed an ongoing understanding that they would not poach each other's customers and would follow each other's price increases. Notably, S.E. and Nesta were not friends and communicated almost exclusively by phone.

276. S.E. and Nesta coordinated to allocate the market for Valsartan HCTZ. Valsartan HCTZ, also known by the brand name Diovan, is used to treat high blood pressure.

277. Diovan was a large volume drug that had sales in the United States of approximately \$1.6 billion for the 12 months ending June 30, 2012.

278. Mylan was the first to file an abbreviated new drug application (ANDA) to market the generic version—Valsartan HCTZ—which, if approved, would give Mylan 180 days of generic exclusivity. Sandoz manufactured the authorized generic. This meant that Sandoz and Mylan would be the only two manufacturers of the generic version of the drug for six months.

279. Mylan and Sandoz launched Valsartan HCTZ on the same day—September 21, 2012. In the days leading up to the launch, S.E. and Defendant Nesta spoke at least twenty-one (21) times by phone during which they discussed, among other things, allocating market share for this product. These calls are detailed in the table below:

Date	Call Typ	Target Name	Direction	Contact Name	Duration
9/6/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:20:01
9/6/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:11
9/6/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:00:05
9/6/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:01:18
9/6/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:05:22
9/7/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:00:43
9/7/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:11:35
9/7/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:01:03
9/12/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:22:22
9/12/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:01:35
9/12/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:00:06
9/13/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:11:26
9/13/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:19
9/13/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:57
9/13/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:05:22
9/13/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:03:30
9/14/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:07:36
9/17/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:09
9/17/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:03:32
9/19/2012	Voice	Nesta, Jim (Mylan)	Outgoing	CW-4 (Sandoz)	0:02:40
9/19/2012	Voice	Nesta, Jim (Mylan)	Incoming	CW-4 (Sandoz)	0:00:51

280. During these phone calls, Sandoz and Mylan—through S.E. and Nesta—agreed to divvy up the market so that each competitor obtained roughly a 50% market share.

281. Throughout this time, S.E. also kept her supervisor Armando Kellum, Vice President, Contracting and Business Analytics at Sandoz, regularly informed of her discussions with Nesta and met with Kellum in person to discuss her customer accounts, including a meeting on September 14, 2012.

**E. Mylan Entered a Price Fixing Agreement with Competitors to Fix the Price of Generic Drugs**

282. During the Relevant Period, Mylan entered into and maintained price-fixing agreements with the other major participants in the markets for virtually all of the generic drugs

that it marketed, including but not limited to the generic drugs albuterol sulfate, benazepril, clomipramine, divalproex, propranolol, amiloride HCL/HCTZ, doxazosin mesylate, ketorolac, loperamide HCL, levothyroxine sodium, methotrexate, nadolol, tizanidine, and trifluoperazine HCL (the “Price-Fixed Drugs”).

### 1. Albuterol Sulfate

283. In or around the first half of 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for albuterol sulfate, a bronchodilator used to treat asthma and other respiratory conditions. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

284. As shown below in Figure A, during the Relevant Period, the price at which Mylan sold albuterol sulfate skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug.<sup>39</sup> Figure A shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of albuterol sulfate.

285. Before 2013, pricing for albuterol sulfate had for years remained stable, as is typical in a mature market. However, as shown in Figure A, the price of albuterol sulfate charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug

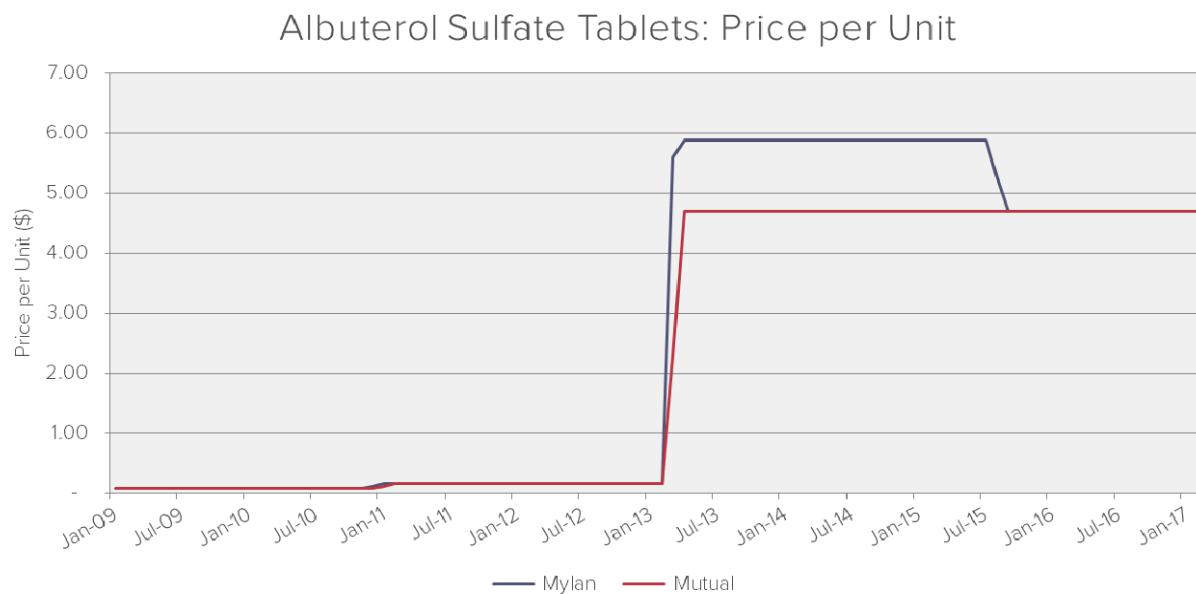
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<sup>39</sup> Figures A-N are based Wholesale Acquisition Cost (“WAC”) data obtained from Symphony Health Solutions. Each colored line in Figures A-N represents the weighted average price the associated drug marketer charged over time for each unit of the specified drug, averaged across all product strengths sold by the drug marketer for the indicated form of that drug. If a drug marketer held less than 1% of the market for a Fixed-Price Drug, the pricing of that drug marketer was excluded from calculations for the period during which its market share was less than 1%.

companies during which the companies, including Mylan, colluded to fix the price of albuterol sulfate including on February 20-22, 2013 in Orlando, Florida, among other meetings.

286. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure A: Albuterol Sulfate**



287. The magnitude by which Mylan and other marketers of albuterol sulfate increased the price of this drug is likewise telling. The average price of common dosages of albuterol sulfate, as measured by National Drug Acquisition Cost (“NADAC”) data, increased by between 2870% and 4266% during the Relevant Period, and the average price of common dosages of the drug increased by between 2653% and 3911% in a matter of days at some point during the Relevant Period.<sup>40</sup>

<sup>40</sup> The NADAC is based on CMS’s monthly surveys of retail pharmacies to determine average acquisition cost for covered outpatient drugs.

288. Table A below displays percentage increases in NADAC data for common dosages of albuterol sulfate. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on albuterol sulfate—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table A: Albuterol Sulfate**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Albuterol Sulfate 2 MG Tab	2013-05-16	3911%	February 2013	December 2015	4266%
Albuterol Sulfate 4 MG Tab	2013-05-23	2653%	March 2013	March 2013	2870%

## 2. Benazepril

289. In or around the first half of 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for benazepril, an oral medication used to treat high blood pressure. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

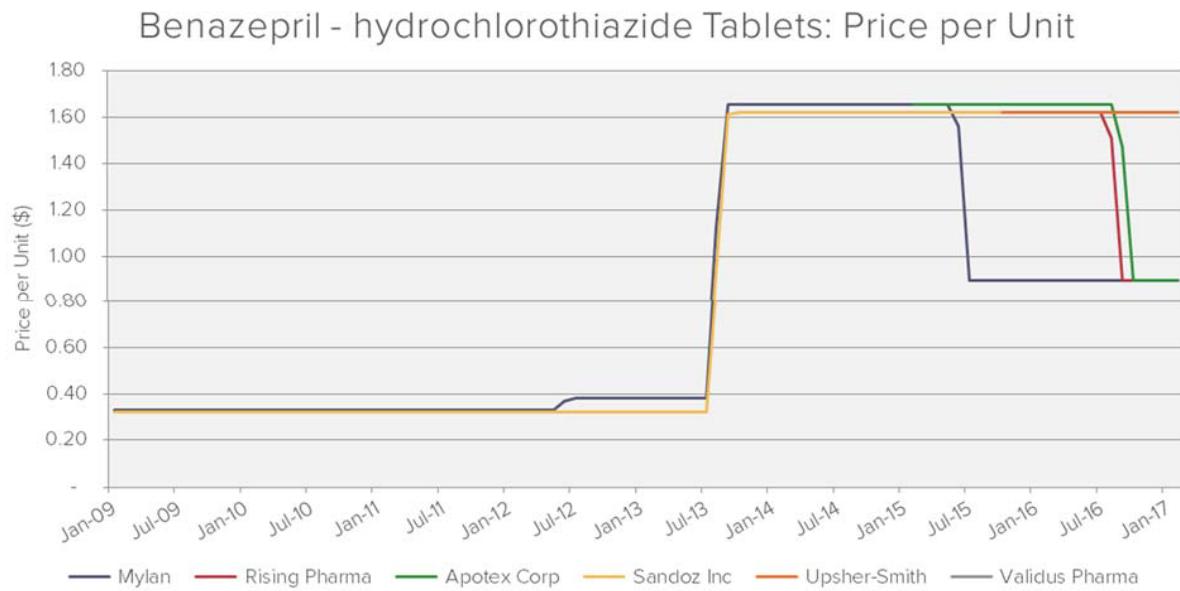
290. As shown below in Figure B, during the Relevant Period, the price at which Mylan sold benazepril skyrocketed over a matter of days in near perfect synchronization with the

price hikes of the other major marketers of this drug. Figure B shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of benazepril.

291. Before 2013, pricing for benazepril had for years remained stable, as is typical in a mature market. However, as shown in Figure B, the price of benazepril charged by all major marketers of this drug, including Mylan, increased dramatically in the months following June 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of benazepril, including on February 20-22, 2013 in Orlando, Florida, and June 4-5, 2013 in Bethesda, Maryland, among other meetings.

292. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure B: Benazepril**



293. The magnitude by which Mylan and other marketers of benazepril increased the price of this drug is likewise telling. The average price of common dosages of benazepril, as measured by NADAC data, increased by between 331% and 402% during the Relevant Period, and the average price of common dosages of the drug increased by between 263% and 368% in a matter of days at some point during the Relevant Period.

294. Table B below displays percentage increases in NADAC data for common dosages of benazepril. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on benazepril—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table B: Benazepril**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Benazepril-Hydrochlorothiazide 10-12.5 MG Tab	2013-11-21	267%	April 2013	November 2014	377%
Benazepril-Hydrochlorothiazide 20-12.5 MG Tab	2013-10-17	263%	March 2013	February 2014	331%
Benazepril-Hydrochlorothiazide 20-25 MG Tab	2013-11-07	263%	October 2013	July 2015	347%
Benazepril-Hydrochlorothiazide 5-6.25 MG Tab	2014-01-22	368%	December 2013	October 2014	402%

### 3. Clomipramine

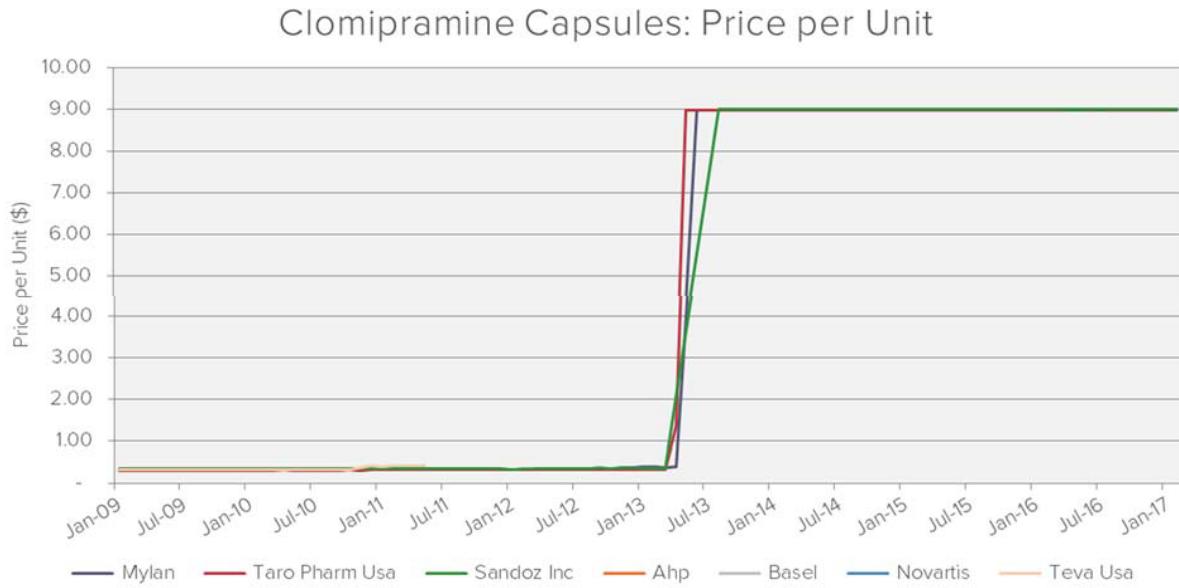
295. In or around the first half of 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for clomipramine, a tricyclic antidepressant used to treat obsessive compulsive disorder, a potentially debilitating mental illness. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

296. As shown below in Figure C, during the Relevant Period, the price at which Mylan sold clomipramine skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure C shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of clomipramine.

297. Before 2013, pricing for clomipramine had for years remained stable, as is typical in a mature market. However, as shown in Figure C, the price of clomipramine charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of clomipramine, including on February 20-22, 2013 in Orlando, Florida, among other meetings.

298. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

#### Figure C: Clomipramine



299. The magnitude by which Mylan and other marketers of clomipramine increased the price of this drug is likewise telling. The average price of common dosages of clomipramine, as measured by NADAC data, increased by between 1973% and 3520% during the Relevant Period, and the average price of common dosages of clomipramine increased by between 1937% and 3482% in a matter of days at some point during the Relevant Period.

300. Table C below displays percentage increases in NADAC data for common dosages of clomipramine. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on clomipramine—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table C: Clomipramine**

Drug Name and Form	Date of Largest %	Largest % Increase	Lowest to Highest %	Lowest to Highest %	Lowest to Highest %
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	Increase in NADAC	in NADAC	increase – LOWEST DATE	Increase – HIGHEST DATE	Increase
Clomipramine 25 MG Capsule	2013-06-13	3482%	April 2013	March 2016	3520%
Clomipramine 50 MG Capsule	2013-06-13	2640%	March 2013	June 2013	2701%
Clomipramine 75 MG Capsule	2013-07-11	1937%	February 2013	November 2013	1973%

#### 4. Divalproex

301. In or around the first half of 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for divalproex, used to treat certain types of seizures and migraines. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

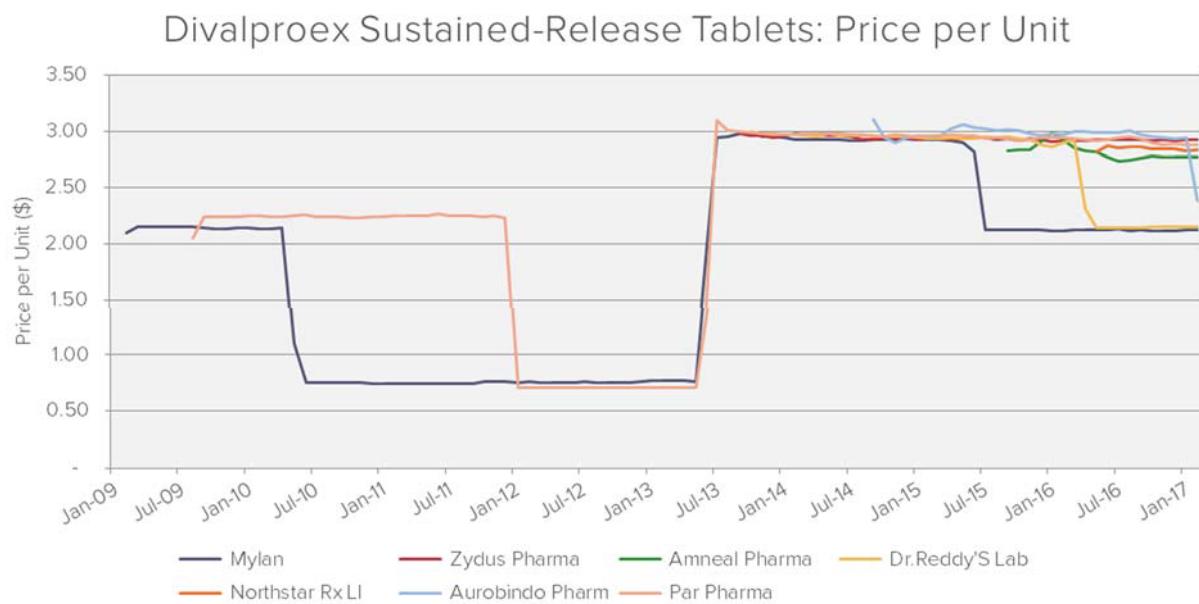
302. As shown below in Figure D, during the Relevant Period, the price at which Mylan sold divalproex skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure D shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of divalproex.

303. Before 2013, pricing for divalproex had for years remained stable, as is typical in a mature market. However, as shown in Figure D, the price of divalproex charged by all major marketers of this drug, including Mylan, increased dramatically in the months following February 2013. This price increase followed meetings of members of generic drug companies during which the companies, including Mylan, colluded to fix the price of divalproex, including

on February 20-22, 2013 in Orlando, Florida, and June 4-5, 2013 in Bethesda, Maryland, among other meetings.

304. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure D: Divalproex**



305. The magnitude by which Mylan and other marketers of divalproex increased the price of this drug is likewise telling. The average price of common dosages divalproex, as measured by NADAC data, increased by between 685% and 1098% during the Relevant Period, and the average price of common dosages of divalproex increased by between 561% and 935% in a matter of days at some point during the Relevant Period.

306. Table D below displays percentage increases in NADAC data for common dosages of divalproex. The column titled “Largest % Increase in NADAC” indicates the largest

monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on divalproex—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table D: Divalproex**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Divalproex Sod ER 250 MG Tab	2013-09-19	561%	March 2013	September 2013	685%
Divalproex Sod ER 500 MG Tab	2013-09-19	935%	June 2013	September 2013	1098%

## 5. Propranolol

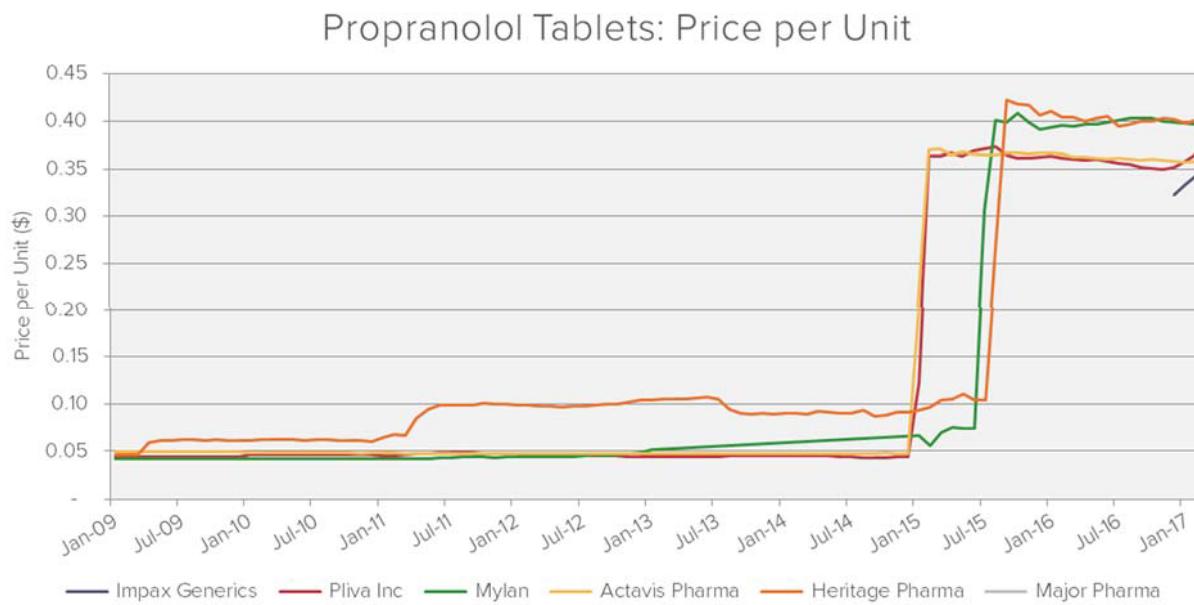
307. In or around 2014 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for propranolol, a beta-blocker used to treat and prevent heart attack and other heart and circulatory conditions. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

308. As shown below in Figure E, during the Relevant Period, the price at which Mylan sold propranolol skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure E shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of propranolol.

309. Before 2015, pricing for propranolol had for years remained stable, as is typical in a mature market. However, as shown in Figure E, the price of propranolol charged by all major marketers of this drug, including Mylan, increased dramatically in spring and fall of 2015.

310. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure E: Propranolol**



311. The magnitude by which Mylan and other marketers of propranolol increased the price of this drug is likewise telling. The average price of common dosages propranolol, as measured by NADAC data, increased by between 832% and 1124% during the Relevant Period, and the average price of common dosages of propranolol increased by between 39% and 356% in a matter of days at some point during the Relevant Period.

312. Table E below displays percentage increases in NADAC data for common dosages of propranolol. The column titled “Largest % Increase in NADAC” indicates the largest

monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on propranolol—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table E: Propranolol**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Propranolol 10 MG Tablet	2015-03-18	210%	December 2014	September 2015	832%
Propranolol 20 MG Tablet	2015-03-18	330%	October 2014	November 2015	1047%
Propranolol 40 MG Tablet	2015-03-18	356%	October 2014	February 2016	1124%
Propranolol 60 MG Tablet	2016-03-23	39%	November 2014	August 2015	111%
Propranolol 80 MG Tablet	2015-03-18	295%	October 2014	November 2015	1113%

313. The sudden, dramatic price increases of the prices for the Price-Fixed Drugs during the Relevant Period cannot be explained by benign market forces. During the Relevant Period, there were no significant increases in the cost of making, no significant decrease in the supply of, and no significant increases in demand for, the Price-Fixed Drugs. Federal law requires drug manufactures to report potential drug shortages to the FDA, the reasons therefor, and the expected duration of the shortage. No supply disruptions were reported to the FDA during the Relevant Period that would explain the price increases. There were no similar price increases in other countries selling these generic drugs.

314. Accordingly, the only plausible explanation for Mylan's raising the prices of the Price-Fixed Drugs suddenly and stratospherically during the Relevant Period is that Mylan was acting in collusion with other generic drug manufacturers to fix the prices for these drugs.

315. These astronomical price increases caused, and continue to cause, significant harm to ordinary consumers, who rely on the Price-Fixed Drugs for their continued well-being. Generic drugs are a critical part of the healthcare system in the United States, comprising nearly 8 in 10 prescriptions filled. A member survey by the NCPA found that the massive increases in the prices of generic drugs "are hurting patients and pharmacies' ability to operate" and that in some cases, "patients are declining their medication due to increased co-pays . . ."<sup>41</sup>

316. On January 14, 2014, David Rekenthaler of Teva coordinated a price increase in propranolol with Defendant Nesta of Mylan and Marc Falkin, Vice President, Marketing, Pricing and Contracts at Actavis Pharma, Inc. ("Actavis"). The timing and duration of those phone calls are set forth in the table below:

Date	Call Typ	Target Name	Direction	Contact Name	Time	Duration
1/14/2015	Voice	Rekenthaler, David (Teva)	Outgoing	Falkin, Marc (Actavis)	3:10:00	0:01:00
1/14/2015	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	3:12:00	0:01:00
1/14/2015	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	5:39:00	0:09:00
1/14/2015	Voice	Rekenthaler, David (Teva)	Outgoing	Falkin, Marc (Actavis)	6:29:00	0:03:00

Teva raised its pricing for propranolol on January 28, 2015, and Actavis' price increase on propranolol became effective on February 17, 2015. Rekenthaler then spoke to Nesta twice on February 18, 2015 and again on February 19, 2015. Mylan ultimately followed the Teva and Actavis price increases for propranolol with a price increase of its own on July 10, 2015.

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<sup>41</sup> National Community Pharmacists Association, Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say (Jan. 8, 2014), available at <http://www.ncpanet.org/newsroom/newsreleases/2014/01/08/genericdrug-price-spikes-demand-congressional-hearing-pharmacists-say>.

## **6. Amiloride Hydrochloride**

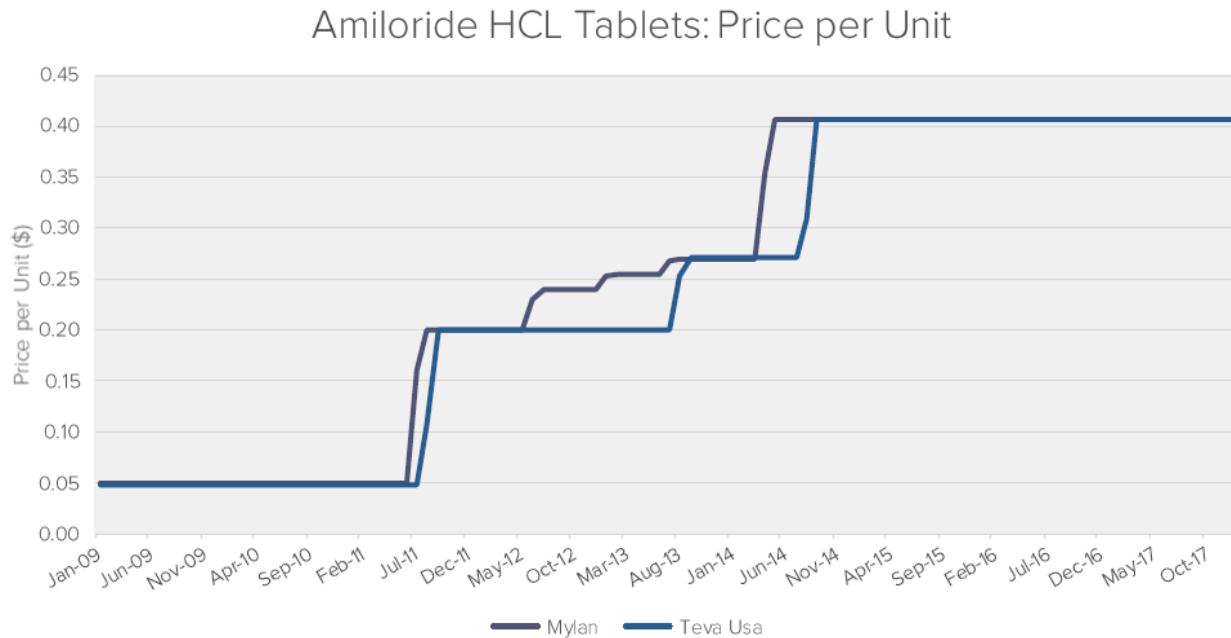
317. In or around 2011 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for amiloride hydrochloride, used to treat high blood pressure (hypertension), heart failure or extra fluid in the body (edema). Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

318. As shown below in Figure F, during the Relevant Period, the price at which Mylan sold amiloride hydrochloride skyrocketed twice in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure F shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of amiloride hydrochloride.

319. Pricing for amiloride hydrochloride had for years remained stable, as is typical in a mature market. However, as shown in Figure F, the price of amiloride hydrochloride charged by all major marketers of this drug, including Mylan, increased dramatically in 2011, in 2013, as well as in 2014-15.

320. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

### **Figure F: Amiloride Hydrochloride**



321. The magnitude by which Mylan and other marketers of amiloride hydrochloride increased the price of this drug is likewise telling. The average price of common dosages amiloride hydrochloride, as measured by NADAC data, increased by between 39% and 90% during the Relevant Period, and the average price of common dosages of amiloride hydrochloride increased by between 20% and 23% in a matter of days at some point during the Relevant Period.

322. Table F below displays percentage increases in NADAC data for common dosages of amiloride hydrochloride. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on amiloride hydrochloride—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table F: Amiloride Hydrochloride**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Amiloride HCL 5 MG Tablet	31/01/2015	20%	31/05/2013	31/01/2015	39%
Amiloride HCL 5-50 MG Tablet	30/06/2014	23%	30/09/2013	31/07/2015	90%

## 7. Doxazosin Mesylate

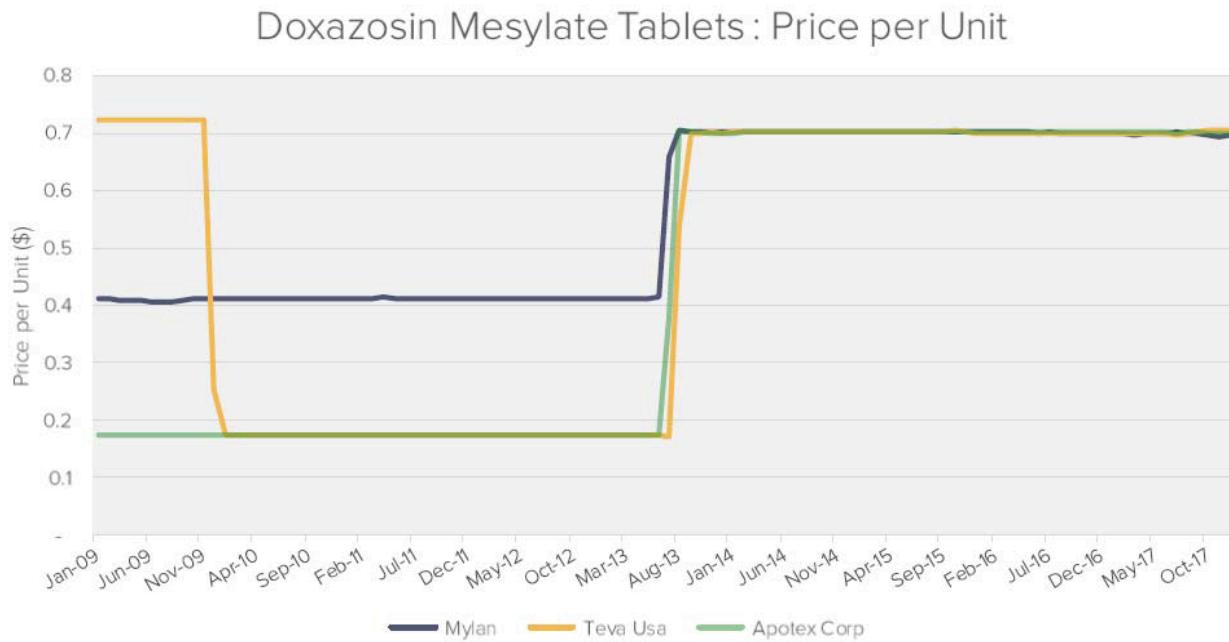
323. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for doxazosin mesylate, an oral medication used to treat symptoms of an enlarged prostate and high blood pressure. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

324. As shown below in Figure G, during the Relevant Period, the price at which Mylan sold doxazosin mesylate skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure G shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of doxazosin mesylate.

325. Pricing for doxazosin mesylate had for years remained stable, as is typical in a mature market. However, as shown in Figure G, the price of doxazosin mesylate charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

326. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure G: Doxazosin Mesylate**



327. The magnitude by which Mylan and other marketers of doxazosin mesylate increased the price of this drug is likewise telling. The average price of common dosages of doxazosin mesylate, as measured by NADAC data, increased by between 529% and 1325% during the Relevant Period, and the average price of common dosages of the drug increased by between 230% and 690% in a matter of days at some point during the Relevant Period.

328. Table G below displays percentage increases in NADAC data for common dosages of doxazosin mesylate. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that

the drug cartel's price hikes on doxazosin mesylate—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table G: Doxazosin Mesylate**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Doxazosin Mesylate 1 MG Tab	31/10/2013	516%	31/05/2013	28/02/2014	1325%
Doxazosin Mesylate 2 MG Tab	31/08/2013	690%	31/03/2013	30/11/2013	1012%
Doxazosin Mesylate 4 MG Tab	31/01/2013	457%	31/03/2013	31/12/2013	831%
Doxazosin Mesylate 8 MG Tab	31/10/2013	230%	31/03/2013	28/02/2014	529%

## 8. Ketorolac

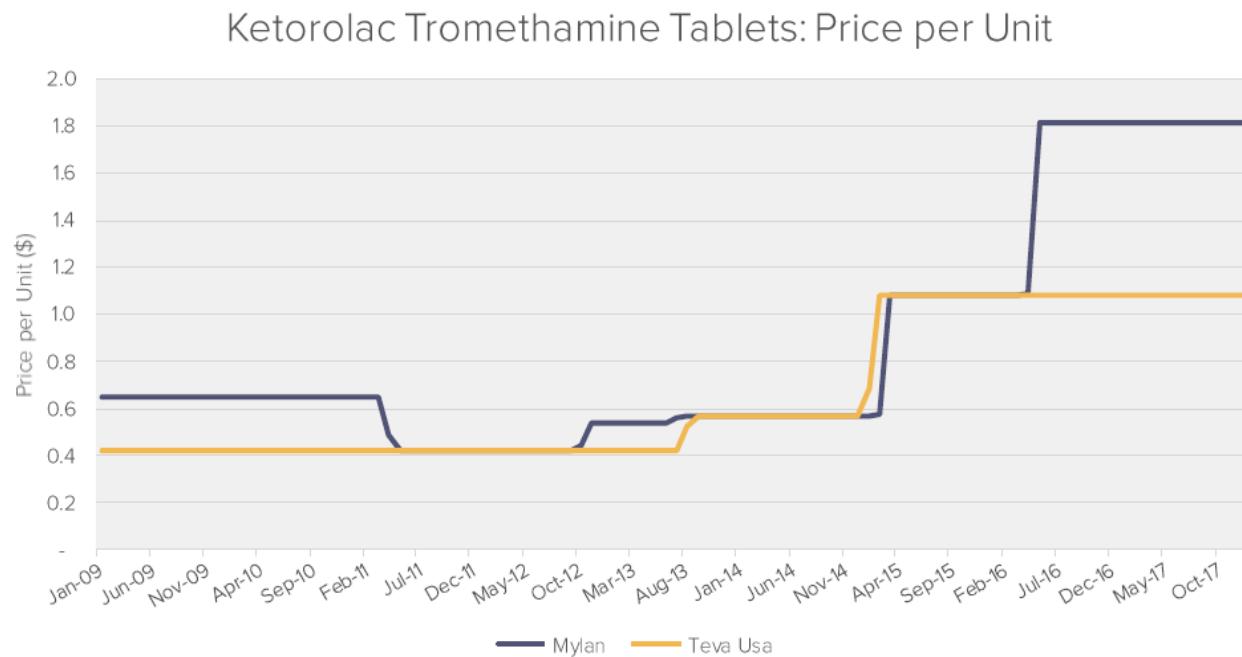
329. In or around 2012 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for ketorolac, used to treat pain. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

330. As shown below in Figure H, during the Relevant Period, the price at which Mylan sold ketorolac skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure H shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of ketorolac.

331. Pricing for ketorolac had for years remained stable, as is typical in a mature market. However, as shown in Figure H, the price of ketorolac charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

332. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure H: Ketorolac**



333. The magnitude by which Mylan and other marketers of ketorolac increased the price of this drug is likewise telling. The average price of a common dosage of ketorolac, as measured by NADAC data, increased by 615% during the Relevant Period, and the average price of a common dosage of ketorolac increased by 192% in a matter of days at some point during the Relevant Period.

334. Table H below displays percentage increases in NADAC data for common dosages of ketorolac. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on ketorolac—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table H: Keterolac**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Ketorolac 10 MG Tablet	31/10/2013	192%	31/05/2013	30/11/2017	615%

#### **9. Loperamide HCL**

335. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for loperamide HCL, used to decrease the frequency of diarrhea. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

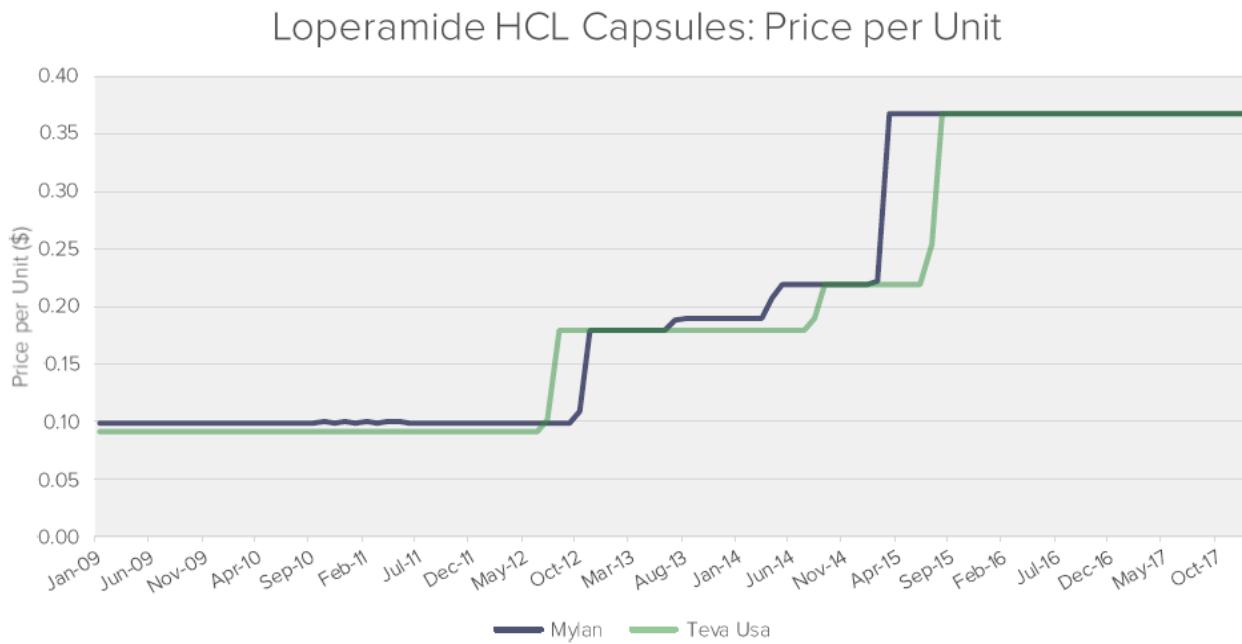
336. As shown below in Figure H, during the Relevant Period, the price at which Mylan sold loperamide HCL skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure I shows an unmistakable

pattern of coordination among generic drug marketers, including Mylan, in the pricing of loperamide HCL.

337. Pricing for loperamide HCL had for years remained stable, as is typical in a mature market. However, as shown in Figure I, the price of loperamide HCL charged by all major marketers of this drug, including Mylan, increased during the Relevant Period.

338. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure I: Loperamide HCL**



339. The magnitude by which Mylan and other marketers of loperamide HCL increased the price of this drug is likewise telling. The average price of a common dosage loperamide HCL, as measured by NADAC data, increased by 159% during the Relevant Period, and the average price of a common dosage of loperamide HCL increased by 364% in a matter of days at some point during the Relevant Period.

340. Table I below displays percentage increases in NADAC data for common dosages of loperamide HCL. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on loperamide HCL—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table I: Loperamide HCL**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Loperamide 2 MG Capsule	31/10/2014	364%	31/10/2013	31/01/2016	159%

## **10. Levothyroxine Sodium**

341. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for levothyroxine sodium, used to treat thyroid hormone deficiency. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

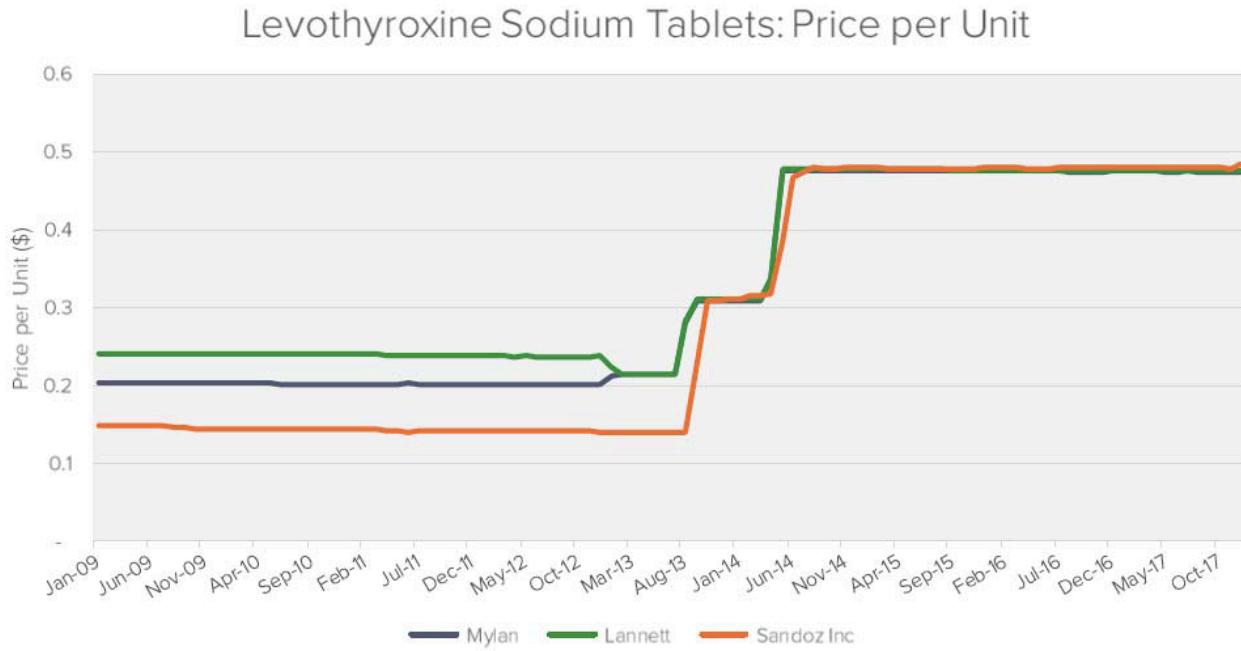
342. As shown below in Figure J, during the Relevant Period, the price at which Mylan sold levothyroxine sodium skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure J shows an unmistakable

pattern of coordination among generic drug marketers, including Mylan, in the pricing of levothyroxine sodium.

343. Pricing for levothyroxine sodium had for years remained stable, as is typical in a mature market. However, as shown in Figure J, the price of levothyroxine sodium charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

344. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure J: Levothyroxine Sodium**



345. The magnitude by which Mylan and other marketers of levothyroxine sodium increased the price of this drug is likewise telling. The average price of common dosages levothyroxine sodium, as measured by NADAC data, increased by between 239% and 303%

during the Relevant Period, and the average price of common dosages of levothyroxine sodium increased by between 536% and 936% in a matter of days at some point during the Relevant Period.

346. Table J below displays percentage increases in NADAC data for common dosages of levothyroxine sodium. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on levothyroxine sodium—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table J: Levothyroxine Sodium**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Levothyroxine 25 MCG Tablet	30/11/2013	720%	28/02/2013	30/09/2014	291%
Levothyroxine 50 MCG Tablet	30/11/2013	936%	28/02/2013	28/02/2015	303%
Levothyroxine 75 MCG Tablet	30/11/2013	817%	28/02/2013	30/09/2014	294%
Levothyroxine 88 MCG Tablet	30/11/2013	809%	28/02/2013	30/09/2014	294%
Levothyroxine 100 MCG Tablet	30/11/2013	831%	28/02/2013	30/09/2014	303%
Levothyroxine 112 MCG Tablet	30/11/2013	866%	28/02/2013	31/08/2014	298%
Levothyroxine 125 MCG Tablet	30/11/2013	864%	28/02/2013	31/08/2014	296%
Levothyroxine 137 MCG Tablet	30/11/2013	628%	28/02/2013	30/09/2014	239%
Levothyroxine 150 MCG Tablet	30/11/2013	889%	28/02/2013	30/09/2014	286%

Levothyroxine 175 MCG Tablet	30/11/2013	840%	28/02/2013	31/08/2014	294%
Levothyroxine 200 MCG Tablet	30/11/2013	742%	28/02/2013	31/08/2014	277%
Levothyroxine 300 MCG Tablet	30/11/2013	536%	31/03/2013	31/08/2014	247%

## 11. Methotrexate

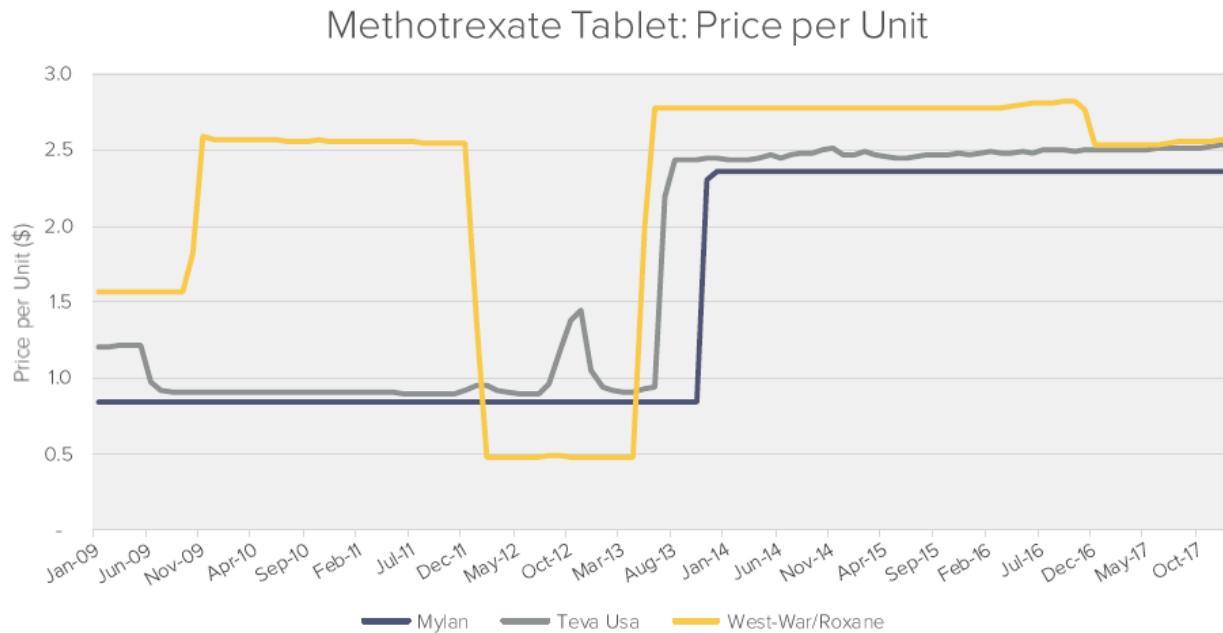
347. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for methotrexate, used to treat cancer, autoimmune diseases, ectopic pregnancy, and for medical abortions. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

348. As shown below in Figure K, during the Relevant Period, the price at which Mylan sold methotrexate skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure K shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of methotrexate.

349. Pricing for methotrexate had for years remained stable, as is typical in a mature market. However, as shown in Figure K, the price of methotrexate charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

350. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure K: Methotrexate**



351. The magnitude by which Mylan and other marketers of methotrexate increased the price of this drug is likewise telling. The average price of a common dosage of methotrexate, as measured by NADAC data, increased by between 423% during the Relevant Period, and the average price of a common dosage of methotrexate increased by 308% in a matter of days at some point during the Relevant Period.

352. Table K below displays percentage increases in NADAC data for common dosages of methotrexate. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on methotrexate—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table K: Methotrexate – FIX**

Drug Name and Form	Date of	Largest %	Lowest to	Lowest to	Lowest to
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	Largest % Increase in NADAC	Increase in NADAC	Highest % increase – LOWEST DATE	Highest % Increase – HIGHEST DATE	Highest % Increase
Methotrexate 2.5 MG Tablet	30/06/2013	308%	28/02/2013	31/07/2013	423%

## 12. Nadolol

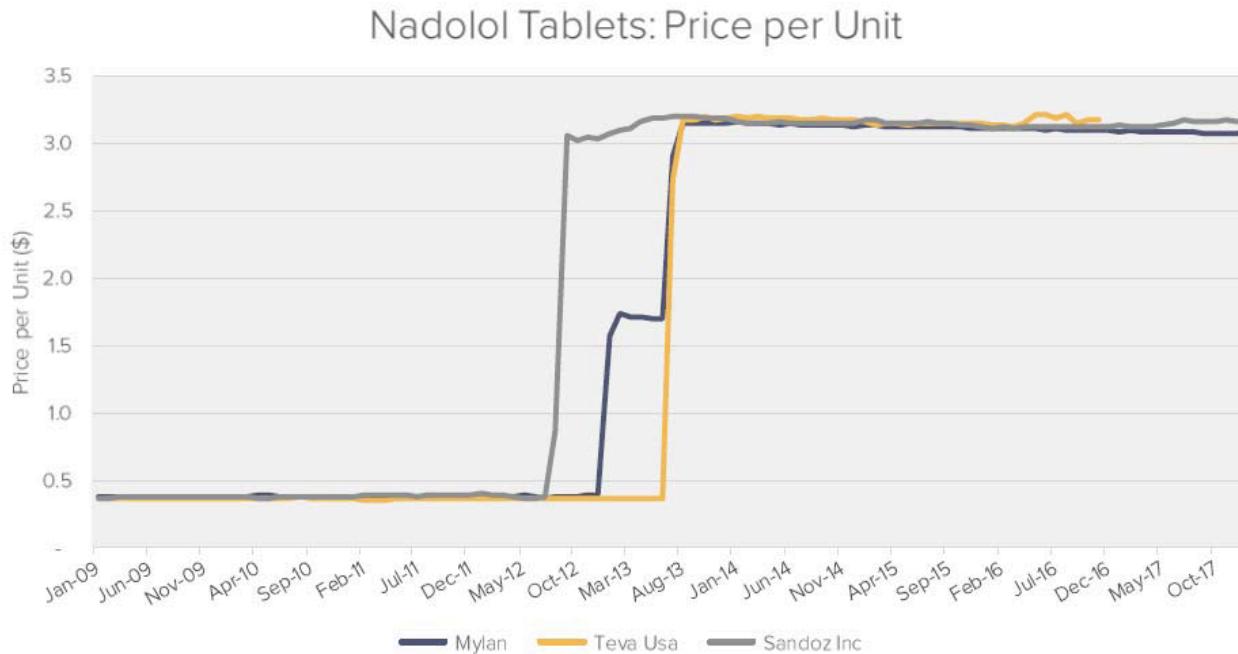
353. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for nadolol, used to treat high blood pressure, heart pain, and atrial fibrillation. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

354. As shown below in Figure L, during the Relevant Period, the price at which Mylan sold nadolol skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure L shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of nadolol.

355. Pricing for nadolol had for years remained stable, as is typical in a mature market. However, as shown in Figure L, the price of nadolol charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

356. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

### Figure L: Nadolol



357. The magnitude by which Mylan and other marketers of nadolol increased the price of this drug is likewise telling. The average price of common dosages nadolol, as measured by NADAC data, increased by between 39% and 102% in a matter of days at some point during the Relevant Period.

358. Table L below displays percentage increases in NADAC data for common dosages of nadolol. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on nadolol—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table L: Nadolol**

Drug Name and Form	Date of Largest % Increase in	Largest % Increase in	Lowest to Highest % increase –	Lowest to Highest % Increase –	Lowest to Highest % Increase
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	NADAC	NADAC	LOWEST DATE	HIGHEST DATE	
Nadolol 20 MG Tablet	30/09/2013	77%	N/A	N/A	N/A
Nadolol 40 MG Tablet	30/09/2013	102%	N/A	N/A	N/A
Nadolol 80 MG Tablet	30/11/2013	39%	N/A	N/A	N/A

359. In 2012 and 2013, Mylan's only competitors for Nadolol were Teva and Sandoz. All three companies experienced supply problems of some sort during that time period, but they were in continuous communication to coordinate pricing and market allocation in order to maintain market stability. Nadolol was a high volume drug and one of the most profitable drugs where Mylan, Teva, and Sandoz overlapped, so it was very important that they maintain their coordination.

360. By 2012 an anticompetitive understanding among those companies was firmly entrenched. Teva raised its price on Nadolol on July 31, 2012. In the days leading up to that increase—following a pattern that would become routine and systematic over the following years—Kevin Green, at the time in the sales department at Teva, was in frequent communication with executives at both Sandoz and Mylan. Green spoke to an employee from Sandoz twice on July 29, 2012, and again on the day of the price increase, July 31, 2012. Similarly, Green was communicating with Defendant Nesta of Mylan often in the days leading up to the increase, including five (5) calls on the day of the price increase. Sandoz followed with its own increase on August 27, 2012. The increases were staggering—varying from 746% to 2,762% depending on the formulation. The day before the Sandoz increase, Armando Kellum, then the Senior Director of Pricing and Contracts at Sandoz, called Green. They had also spoken once earlier in the month, shortly after the Teva increase. The Sandoz employee also called Green twice on August 21, 2012—the same day that Sandoz requested approval from its Pricing Committee to

raise the Nadolol price. The day after the Sandoz increase, Green—acting as the conduit of information between Sandoz and Mylan—called Nesta of Mylan twice, with one call lasting fourteen (14) minutes. Mylan, which returned to the market after a brief supply disruption, followed and matched the Teva and Sandoz increases on January 4, 2013. In what had become a routine component of the scheme, the day before the Mylan increase Nesta spoke to Green four (4) times. The next day, Green conveyed the information he had learned from Nesta directly to his counterpart at Sandoz. On January 4, 2013—the day of the Mylan increase—Green called Kellum twice in the morning, including a six (6) minute call at 9:43 AM.

361. Green was not speaking with his Sandoz contacts solely about Nadolol, the common drug between Teva and Sandoz, but was also conveying information to Sandoz about a Mylan price increase on another drug that Teva did not even sell—Levothyroxine. Such conversations further demonstrate the broad, longstanding agreement among each of these competitors to share market intelligence in order to facilitate the scheme.

### **13. Tizanidine**

362. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for tizanidine, used to treat muscle spasticity due to spinal cord injury or multiple sclerosis. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

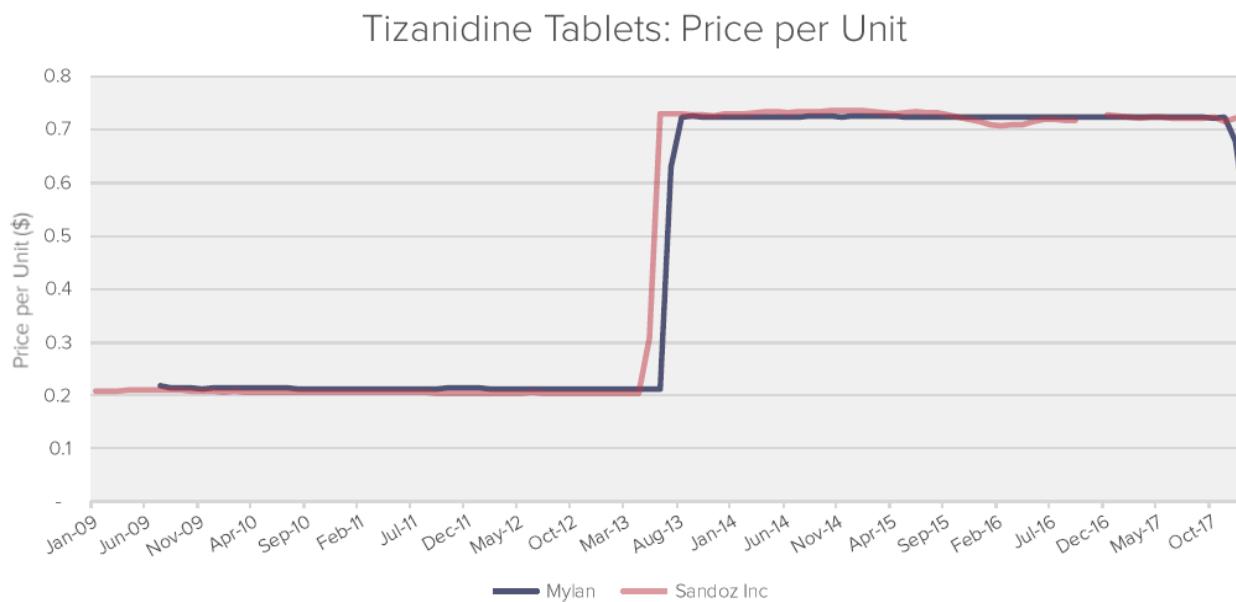
363. As shown below in Figure M, during the Relevant Period, the price at which Mylan sold tizanidine skyrocketed over a matter of days in near perfect synchronization with the

price hikes of the other major marketers of this drug. Figure M shows an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of tizanidine.

364. Pricing for tizanidine had for years remained stable, as is typical in a mature market. However, as shown in Figure M, the price of tizanidine charged by all major marketers of this drug, including Mylan, increased dramatically in during the Relevant Period.

365. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure M: Tizanidine**



366. The magnitude by which Mylan and other marketers of tizanidine increased the price of this drug is likewise telling. The average price of common dosages tizanidine, as measured by NADAC data, increased by between 584% and 619% during the Relevant Period, and the average price of common dosages of tizanidine increased by between 17% and 23% in a matter of days at some point during the Relevant Period.

367. Table M below displays percentage increases in NADAC data for common dosages of tizanidine. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on tizanidine—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table M: Tizanidine**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Tizanidine Hcl 2 MG Capsule	30/09/2013	23%	31/03/2013	28/02/2015	584%
Tizanidine Hcl 4 MG Capsule	31/03/2015	17%	31/05/2013	30/09/2013	619%

#### **14. Trifluoperazine HCL**

368. In or around 2013 and continuing throughout the Relevant Period, Mylan entered into and maintained a price-fixing agreement with the other major participants in the market for trifluoperazine HCL, used to treat schizophrenia. Senior executives, including Defendant Bresch, entered the agreement and maintained compliance with it. Defendants Bresch, Malik, Parks, and Nesta were aware of this agreement, which, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, remained in effect until at least June 17, 2019.

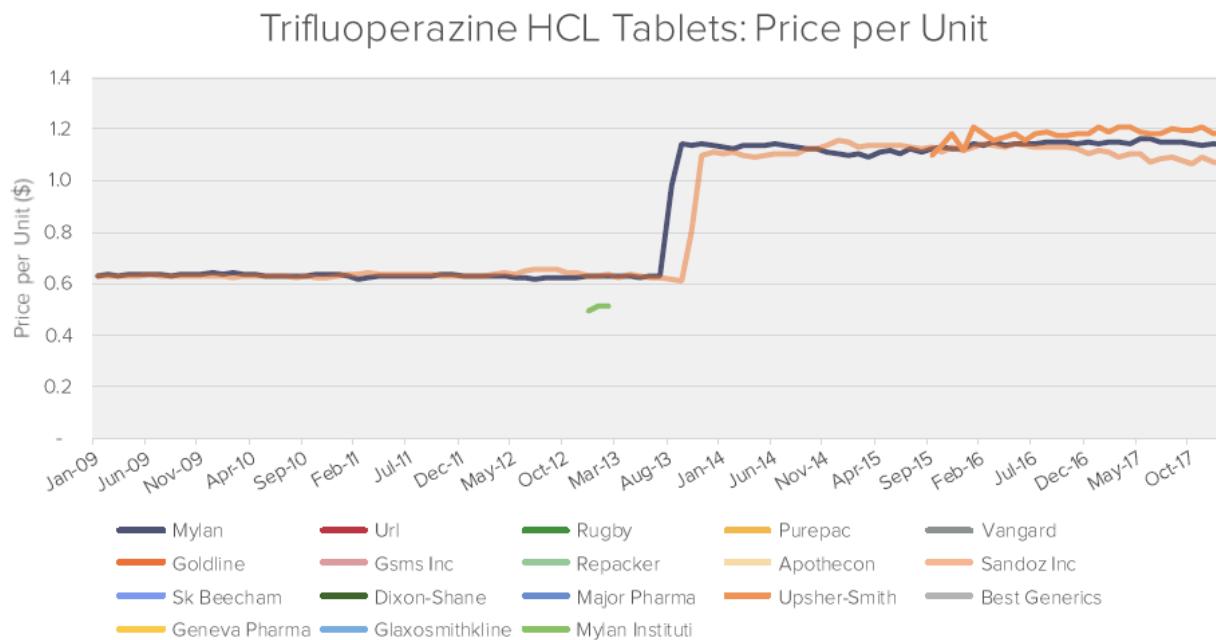
369. As shown below in Figure N, during the Relevant Period, the price at which Mylan sold trifluoperazine HCL skyrocketed over a matter of days in near perfect synchronization with the price hikes of the other major marketers of this drug. Figure N shows

an unmistakable pattern of coordination among generic drug marketers, including Mylan, in the pricing of trifluoperazine HCL.

370. Pricing for trifluoperazine HCL had for years remained stable, as is typical in a mature market. However, as shown in Figure N, the price of trifluoperazine HCL charged by all major marketers of this drug, including Mylan, increased dramatically during the Relevant Period.

371. The price increases appear to reflect a “one-way ratchet”: prices never decreased following the initial price increases to the extent one would expect if sudden price increases reflected temporary supply shortages, cost increases, or other benign market explanations.

**Figure N: Trifluoperazine HCL**



372. The magnitude by which Mylan and other marketers of trifluoperazine HCL increased the price of this drug is likewise telling. The average price of common dosages trifluoperazine HCL, as measured by NADAC data, increased by between 213% and 232%

during the Relevant Period, and the average price of common dosages of trifluoperazine HCL increased by between 96% and 188% in a matter of days at some point during the Relevant Period.

373. Table N below displays percentage increases in NADAC data for common dosages of trifluoperazine HCL. The column titled “Largest % Increase in NADAC” indicates the largest monthly increase observed in the NADAC data set for the named drug. The column titled “Lowest to Highest % Increase” indicates the difference between the highest and lowest prices in the NADAC data set for the named drug during the Relevant Period. This table makes clear that the drug cartel’s price hikes on trifluoperazine HCL—price hikes in which Mylan was an active and voluntary participant—were sudden and astronomical.

**Table N: Trifluoperazine HCL**

Drug Name and Form	Date of Largest % Increase in NADAC	Largest % Increase in NADAC	Lowest to Highest % increase – LOWEST DATE	Lowest to Highest % Increase – HIGHEST DATE	Lowest to Highest % Increase
Trifluoperazine 1 MG Tablet	31/01/2014	188%	30/04/2013	31/01/2014	223%
Trifluoperazine 10 MG Tablet	31/12/2013	96%	30/04/2013	30/09/2016	232%
Trifluoperazine 2 MG Tablet	31/12/2013	181%	30/11/2013	31/03/2015	213%
Trifluoperazine 5 MG Tablet	31/12/2013	109%	31/03/2013	31/03/2015	229%

**F. Mylan’s Price Increases on Generic Drugs Would Have Been Against its Self-interest in the Absence of Price Collusion**

374. Mylan’s price increases on generic drugs, including, but not limited to, the Price-Fixed Drugs, would have been against its self-interest in the absence of price collusion. Generic drugs, including the Price-Fixed Drugs, are a commodity, with any generic drug substitutable

with another, and differentiated competitively with each other primarily based on price. In a market free of collusion, if one generic drug marketer raises its prices significantly above those of its competitors, that marketer will lose market share. Yet as explained above, Mylan and other drug marketers increased the prices of numerous generic drugs substantially during the Relevant Period.

#### **G. Mylan and Teva Conspired to Fix the Prices of Generic Drugs**

375. Certain details concerning how Mylan conspired with one of its co-conspirators, Teva, to fix the prices of generic drugs, are already clear.

376. Nisha Patel worked as a Director for Strategic Customer Marketing and as a Director of National Accounts at Teva. Immediately after she began at Teva, Patel began to investigate Mylan drugs as a potential source for coordinated price increases. For example, on May 6, 2013, as she was creating the list of candidates, Patel sent Kevin Green at Teva an email with an attached spreadsheet. Patel asked Green for certain, specific items that she had highlighted in blue, including nine (9) Mylan drugs: Tolmetin Sodium Capsules; Doxazosin Mesylate Tablets; Methotrexate Tablets; Diltiazem HCL Tablets; Flurbiprofen Tablets; Nadolol Tablets; Amiloride HCLIHCTZ Tablets; Cimetidine Tablets; and Estradiol Tablets.

377. The next day, May 7, 2013, Green spoke to Defendant Nesta at Mylan three times, including one call lasting more than eleven (11) minutes. Green also called Patel twice that day to report on what he had learned. Green and Nesta also spoke a number of times over the next several days, including on May 8 (3:46), May 9 (4:05) and May 10, 2013 (0:28; 10:46 and 2:19).

378. On May 14, 2013, Patel asked several Teva national account managers, including Green, to obtain information on certain Mylan drugs, including Cimetidine and Nadolol in

preparation for a potential price increase. On May 17, 2013, Green spoke to Defendant Nesta six (6) times, including calls lasting 11:50, 2:23, 4:25 and 16:02.

379. On May 29, 2013, after a discussion with Maureen Cavanaugh, Senior Vice President, Commercial Officer, North America at Teva, Patel added four Mylan drugs to the Teva price increase list: Nadolol, Cimetidine, Prazosin and Methotrexate.

380. Discussions between Green and Nesta about specific drugs continued into June, as Mylan was also preparing for its own major price increase on a number of drugs. From June 24 through June 28, 2013, for example, Green and Nesta had at least the following telephone calls:

Date	Call Typ	Target Name	Direction	Contact Name	Time	Duration
6/24/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	13:25:29	0:00:06
6/24/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	13:32:25	0:10:13
6/25/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	13:43:27	0:00:06
6/25/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	16:02:58	0:00:32
6/25/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	16:51:43	0:00:03
6/26/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	9:55:29	1:00:25
6/27/2013	Voice	Nesta, Jim (Mylan)	Incoming	Green, Kevin (Teva)	10:47:23	0:00:06
6/27/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	11:04:04	0:01:03
6/27/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	15:42:07	0:04:20
6/28/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	10:59:56	0:03:53

381. On June 26, 2013, in the midst of this flurry of communications between Teva and Mylan (and the same day that Green and Nesta had a one-hour phone call), one of Patel's colleagues sent her a suggestion with the following list of potential drugs to add to the price increase list:

<u>Product</u>	<u>Competitors (Mkt Share)</u>
Disopyramide Phosphate Capsules	Actavis (61%)
Ketorolac Tablets	Mylan (32%)
Ketoprofen Capsules	Mylan (63%)
Hydroxyzine Pamoate Capsules	Sandoz (39%); Actavis (9%)
Nystatin Tablets	Heritage (35%); Mutual (32%)

Patel responded favorably with regard to some of the drugs, alluding to the fact that she had inside information about at least ketoprofen. At that time, Nystatin was not considered a strong candidate for a price increase because of the quality of the competitors in the market. Those dynamics would later change after Patel struck up a collusive relationship with a high-level executive at Heritage.

382. Mylan raised its price for both Keterolac and Ketoprofen (the two Mylan drugs on the list above) six days later, on July 2, 2013. Teva then quickly followed with its own price increase for both drugs (and others) on August 9, 2013. Those price increases were closely coordinated and agreed to by Teva and Mylan.

383. At the end of the flurry of phone communications between Teva and Mylan described above, on June 28, 2013 Green and Defendant Nesta had a four (4) minute call starting at 10:59 AM. Within minutes after that call, Patel circulated an email internally containing information obtained directly from Green, but got one significant point wrong (which confirms that she had advance notice of the Mylan increase). In actuality, Mylan did not announce the price increase until the following Monday, July 1, 2013—with an effective date of July 2, 2013.

384. Patel consistently used a code word in e-mails to camouflage the fact that she and her co-conspirators within Teva were communicating with competitors about future price increases. She used the code word when discussing Taro in a May 24, 2013 spreadsheet relating to pricing, after speaking with Aprahamian and before Taro raised its price on Adapalene Gel. She used it again on June 26, 2013—after Green and Nesta spoke several times in advance of Mylan’s price increase on Ketoprofen.

385. Similarly on July 2, 2013—the day before Teva’s price increases (including for the drug Methotrexate) went into effect, a colleague asked Patel how Teva’s competitors’ pricing compared with regard to Methotrexate. Patel responded that Mylan’s pricing was a little low on that drug, so Teva felt comfortable increasing the price of that drug on July 3, 2013. These predictions—which were based on the direct communications between Green and Nesta noted above—again turned out to be accurate: Mylan increased its price of Methotrexate pursuant to its agreement with Teva, on November 15, 2013.

386. Teva and Mylan continued to conspire to raise prices together. Teva and Mylan were coordinating price increases consistently during this period, including the time leading up to price increases on August 9, 2013. During each step in the process, Teva and Mylan executives kept their co-conspirators apprised of their decisions. The communications were typically initiated by Patel, who asked Green to communicate with Defendant Nesta of Mylan and obtain company positions on many different drugs. But at times, Patel communicated directly with Nesta.

387. For example, on July 22, 2013, Patel sent Green an e-mail with an attached spreadsheet of pricing increase items. A large majority were Mylan drugs.

388. The next day—July 23, 2013—at 4:30 PM, Green and Nesta spoke for more than six (6) minutes. Immediately after hanging up the phone, Green called Patel to convey the intel he had obtained from Mylan. The call lasted more than three (3) minutes.

389. On July 29, 2013, Green at Teva was approached by a large retail pharmacy asking for bids on several of the drugs that Mylan had increased prices on in early July. Green’s first step was to request market share information for those drugs so that Teva could make a

decision on how to respond to the customer's inquiry based on the generally accepted understanding regarding fair share.

390. The next day, July 30, 2013, Patel sent Green the price increase file as an attachment. Patel asked Green to obtain additional information for a group of Mylan drugs, some of which varied slightly from the prior spreadsheet.

391. Following the same consistent pattern, Green and Nesta spoke six (6) times over the next two days. After hanging up from the last call between the two on August 1, 2013, Green called Patel and conveyed the results of his conversations. This series of phone calls is detailed below.

Date	Call Type	Target Name	Direction	Contact Name	Time	Duration
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	14:10:33	0:04:52
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	14:50:57	0:01:09
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	14:54:39	0:03:21
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	14:59:57	0:06:53
7/31/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	16:46:59	0:01:27
8/1/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	11:23:47	0:05:48
8/1/2013	Voice	Nesta, Jim (Mylan)	Outgoing	Green, Kevin (Teva)	12:21:43	0:00:59
8/1/2013	Voice	Patel, Nisha (Teva)	Incoming	Green, Kevin (Teva)	12:29:55	0:02:36

392. In the midst of the phone calls between Green and Nesta on July 31, 2013, Patel sent an e-mail concerning a customer request, with a particular focus on balancing Teva's desire to increase prices against its commitment to adhere to the fair share agreement, as well as how that may affect Teva's market share for certain products sold by Mylan.

393. Based on all these communications between Mylan and Teva (and at times other competitors), Mylan and Teva successfully increased the prices on seven different drugs on August 9, 2013.

394. Effective April 17, 2014, Mylan increased its wholesale acquisition cost ("WAC") pricing on a number of different drugs, including several that overlapped with Teva. Mylan also

increased its contract prices, but at least some of those price increases would not become effective until mid-May 2014. Pursuant to the established understanding between the two companies, Teva immediately decided that it would follow the Mylan increases. On April 21, 2014, T.S., a national account executive at Teva, forwarded to Patel two spreadsheets with WAC and average wholesale pricing information for the price increases taken by Mylan. The spreadsheets were created by Mylan personnel. Patel, in turn, forwarded the e-mail to the Teva sales team. Patel's email referenced a list that included the following products, several of which had been the subject of coordinated price increases in 2013 as well: amiloride HCL/HCTZ tablets; cimetidine tablets; enalapril maleate tablets; fluvastatin; sodium capsules; loperamide HCL capsules; prazosin HCL capsules; and sotalol hydrochloride tablets. Within days, Teva began receiving requests from its customers for bids due to the Mylan price increases. On April 24, 2014, Patel began to formulate a response to those requests, but noted that Teva was aware of the Mylan customer contract price points, which were not publicly available. Previously, Patel had relied on Kevin Green to obtain specific Mylan customer price points through his communications with Nesta of Mylan, which she used to follow Mylan's pricing. The next day, in a follow-up email about the Mylan strategy, Patel noted that one of her Mylan increase strategies would not have been appropriate for this situation.

395. Patel continued to push for specific contract price points from Mylan. On April 28, 2014, Patel sent an e-mail to the Teva sales team. On May 9, 2014, Patel sent another e-mail to Rekenthaler. Shortly after receiving that e-mail—at 11:15 AM that morning—Rekenthaler called Defendant Nesta at Mylan and left a message. Nesta returned the call at 11:23 AM, and the two spoke for nearly eight (8) minutes.

396. Separately, and before Rekenthaler was able to convey any information he had obtained, Patel forwarded a customer request from ABC (relating to the Mylan increase items) directly to T.S. at Teva, lamenting the absence of Green to obtain the Mylan intel. The next day, T.S. sent Patel an e-mail with an attached spreadsheet listing the Mylan contract price points for all of the recent increases. The spreadsheet attached to her email was created by a Mylan employee.

397. Rekenthaler and Nesta spoke again on May 20, 2014. Patel was more confident that Teva could follow the Mylan price increases exactly, without disrupting the market. That same day, as Patel began to create a new list of Teva price increase candidates, she instructed a colleague to include the Mylan increase drugs—with specific price points—as its own separate tab in the spreadsheet, called “follow.” Her colleague provided the list, as requested, on May 21.

398. On May 21, 2014, Rekenthaler and Nesta spoke twice, including one call lasting nearly four (4) minutes. By May 28, Teva had a much more comprehensive list of price increase items. On that list, seven of the Mylan items were prominently listed.

399. Also on the list were three additional Mylan drugs for which Teva would be leading the price increase: Diclofenac Potassium Tablets; Flubiprofen Tablets; and Prochlorperazine Tablets. With the list firmly squared away at the end of May, Rekenthaler and Nesta had no need to speak again until August, when Teva was preparing to implement the price increases. In the weeks leading up to the August 28, 2014 Teva price increases, Rekenthaler and Nesta spoke several times to coordinate, including at least the calls set forth below:

Date	Call Type	Target Name	Direction	Contact Name	Duration
8/4/2014	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	0:01:00
8/4/2014	Voice	Rekenthaler, David (Teva)	Incoming	Nesta, Jim (Mylan)	0:06:00
8/7/2014	Voice	Rekenthaler, David (Teva)	Incoming	Nesta, Jim (Mylan)	0:14:00
8/11/2014	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	0:02:00
8/11/2014	Voice	Rekenthaler, David (Teva)	Incoming	Nesta, Jim (Mylan)	0:06:00
8/18/2014	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	0:01:00
8/18/2014	Voice	Rekenthaler, David (Teva)	Incoming	Nesta, Jim (Mylan)	0:13:00
8/21/2014	Voice	Rekenthaler, David (Teva)	Outgoing	Nesta, Jim (Mylan)	0:06

400. Representatives from Mylan, Teva, Sandoz, and various other generic drug manufacturers met in Boston, Massachusetts from August 23-26, 2014 for the National Association of Chain Drug Stores annual event, which was the largest pharmaceutical industry meeting of the year.

**H. Mylan’s Co-Conspirator Teva Considered Mylan to be its “Highest Quality Competitor,” i.e., the Company Most Willing to Conspire to Fix Prices**

401. In 2013, Nisha Patel at Teva decided to rank generic drug manufacturers by their willingness to conspire to fix the prices of generic drugs. By May 6, 2013, Patel had completed an initial ranking of fifty-six (56) different manufacturers in the generic drug market by their “quality.” Patel defined “quality” by her assessment of the “strength” of a competitor as a leader or follower for price increases. Ranking was done numerically, from a +3 ranking for the “highest quality” competitor to a -3 ranking for the “lowest quality” competitor.

402. Patel created a formula, which heavily weighted those numerical ratings assigned to each competitor based on their “quality,” combined with a numerical score based on the number of competitors in the market and certain other factors. According to her formula, the best possible candidate for a price increase would be a drug where there was only one other competitor in the market, which would be leading an increase, and where the competitor was the highest “quality.” Conversely, a Teva price increase in drug market with several “low quality”

competitors would not be a good candidate due to the potential that low quality competitors might not follow Teva's price increase and instead use the opportunity to steal Teva's market share. Notably, the companies with the highest rankings at this time were companies with whom Patel and other executives within Teva had significant relationships.

403. The highest quality competitors in Patel's rankings were competitors where Teva had agreements to lead and follow each other's price increases. The agreements and understandings regarding price increases were what made each of those competitors a high quality competitor. As part of their understandings, those competitors also agreed that they would not seek to compete for market share after a Teva price increase.

404. Mylan was Teva's highest-ranked competitor by "quality." The relationship between these two competitors was longstanding, and deeply engrained. It survived changes in personnel over time, and pre-dated Patel's creation of the quality competitor rankings. Kevin Green, who was employed by Teva beginning in 2006 through late October 2013, first began communicating with Defendant Nesta of Mylan by telephone on February 21, 2012. From that time until the time that Green left Teva, Green and Nesta were in almost constant communication, speaking by phone at least 392 times, and exchanging at least twelve (12) text messages—including at or around every significant price increase taken by either company. This amounts to an average of nearly one call or text message every business day during this period.

405. Shortly after Patel started her employment at Teva, she called Defendant Nesta on May 10, 2013 and the two spoke for over five (5) minutes. Because Green had already established a relationship with Mylan, Patel did not need to speak directly with Nesta very often. Typically, Patel would e-mail Green and ask him to obtain market intelligence about certain Mylan drugs; Green would then speak to Nesta—often about a long list of drugs—and report his

findings back to Patel. When Green left Teva to join Zydus Pharmaceuticals (USA), Inc. in late October 2013, the institutional relationship and understanding between Teva and Mylan remained strong. Rekenthaler promptly took over the role of communicating with Defendant Nesta. Starting in December 2013, through the time that Rekenthaler left Teva in April, 2015, Rekenthaler spoke to Nesta 100 times. Prior to Green leaving Teva in late-October 2013, Rekenthaler and Nesta had only spoken by phone once, more than a year earlier in 2012.

### **I. The Structure of the Generic Drug Market Facilitated Mylan's Collusion**

406. From at least 2013 to the 2019, the market structure for the Price-Fixed Drugs was highly conducive to the formation and maintenance of a price-fixing conspiracy. Publicly available data on the markets for the Price-Fixed Drugs in the United States demonstrate that each is susceptible to cartelization by Mylan and other generic drug marketers. Factors that make the markets for the Price-Fixed Drugs highly susceptible to collusion include: (1) a high degree of industry concentration; (2) high barriers to entry; (3) demand inelasticity; (4) the lack of available substitutes; (5) a high degree of interchangeability between the goods of cartel participants; (6) ease of, and opportunities for intercompetitor contacts and communication; (7) sufficient numbers to drive competition; (8) absence of departures from the market; (9) absence of non-conspiring competitors; (10) size of price increases; and (11) reimbursement of generic drugs.

#### **1. High Degree of Industry Concentration**

407. The markets for the Price-Fixed Drugs are highly concentrated and each is dominated by a handful of companies.

408. The commonly accepted measure of market concentration is the Herfindahl-Hirschman Index ("HHI"). The HHI is calculated by squaring the market share of each firm

competing in the market and then summing the resulting numbers. For example, for a market consisting of three firms with shares of 20%, 30%, and 50%, the HHI is 3,800. Federal antitrust enforcement agencies consider markets in which the HHI is above 2,500 to be highly concentrated. In merger reviews, for instance, a proposed merger that would lead to a highly concentrated market, and an increase in the HHI of more than 200 points, creates a presumption of market power and a recognized risk of collusion. Throughout the Relevant Period, the HHI for some or all of the Price-Fixed Drugs was at a level that antitrust enforcement agencies consider indicative of a highly concentrated market vulnerable to collusion.

409. Concentration facilitates collusion because it reduces the number of negotiating partners and increases per-firm collusive profits. Concentration also significantly increases the stability of a cartel. One of the primary difficulties cartels face is cheating: each member has an individual incentive to lower prices slightly below the cartel price to capture significant market share. In a concentrated market, cheating is more easily prevented because each member of the cartel may more easily monitor the others and enforce compliance. In addition, as the number of firms in a market decreases, the probability decreases that firms have different costs and differentiated products, which facilitates cartel formation and maintenance.

## **2. High Barriers to Entry**

410. The presence of significant barriers to entry facilitates the operation of a cartel. Barriers to entry increase a market's susceptibility to a coordinated effort to maintain supracompetitive prices because it is difficult for new suppliers to enter the market and destabilize coordinated supracompetitive prices.

411. Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the markets for the Price-Fixed Drugs. As one of the dominant

players in this market, Mylan, through Defendants Bresch, Malik, Parks, and Nesta and other Mylan employees and executives, were able to fix, raise, and maintain Mylan's prices for the Price-Fixed Drugs without competitive threats from rival generic drug manufacturers.

### **3. Demand Inelasticity**

412. Price elasticity of demand is defined as the measure of responsiveness in the quantity demanded for a product as a result of change in price of the same product. It is a measure of how demand for a product reacts to a change in price. For example, demand is said to be "inelastic" if an increase in the price of a product results in only a small decline, if any, in the quantity sold of that product. In other words, customers have nowhere to turn for alternative, cheaper products of similar quality, and so continue to purchase the produce despite the price increase.

413. For a cartel to profit from raising prices above competitive levels, demand for the product must be relatively inelastic such that any loss in sales will be more than offset by increases in revenue on those sales that are made. Otherwise, increased prices would result in declining sales, revenues, and profits as customers purchased substitute products or declined to buy altogether. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue.

414. The Price-Fixed Drugs are critical to the health of patients; they are considered medical necessities that must be purchased at whatever cost that Mylan offers them for sale. Thus, the Price-Fixed Drugs are excellent candidates for cartelization, because price increases will result in more revenue, rather than less.

415. The Price-Fixed Drugs are necessary treatment for millions of patients for which no substitutes are available. The Price-Fixed Drugs are thus particularly susceptible to collusive

price fixing as price increases will not result in such a loss of sales as to reduce profits, but instead will result in more profits for cartel members.

#### **4. Lack of Available Substitutes**

416. Many patients are unable to substitute other medications for the Price-Fixed Drugs. In some cases, the Price-Fixed Drugs are the only effective treatment for their conditions.

#### **5. High Degree of Interchangeability of Generic Drug Products**

417. A commodity-like product is one that is standardized across suppliers and allows for a high degree of substitutability among different suppliers in the market. When products offered by different suppliers are viewed as interchangeable by purchasers, it is easier for the suppliers to agree on prices for the good in question and it is easier to monitor these prices effectively.

418. The Price-Fixed Drugs are commodity products. Therefore, the products are interchangeable, as they contain the same chemical compounds made from the same raw materials and are therapeutically equivalent. This characteristic facilitates collusion because cartel members can more easily monitor and detect deviations from a price-fixing agreement. In addition, because these are commodity products, each drug manufacturer had to raise prices for the cartel to succeed. Indeed, as explained above, Mylan's raising its prices for the Price-Fixed Drugs was against its individual economic interest because its supposed competitors could have priced below Mylan's price and won substantial market share.

#### **6. Ease of Information Sharing Opportunities for Contact and Communication among Competitors**

419. Mylan and other participants in the cartel communicated their present and future pricing decisions to each other, including in public settings such as earnings calls. By design, Mylan knew what the other cartel participants charged for their generic products, and what each

was going to charge in the future. Price transparency and communications ensured that Mylan and other cartel members could monitor compliance with the cartel, and provided a mechanism by which each could assure the others that they would keep up their end of the bargain.

420. Mylan and other cartel participants are members of the same trade association: the Generic Pharmaceutical Association (“GPhA”). Senior executives of Mylan participate actively in the GPhA. For instance, Defendant Bresch chaired GPhA’s board of directors at all relevant times. Representatives of Mylan and other cartel members met in person at GPhA meetings before and during the Relevant Period, including immediately before certain price increases for the Price-Fixed Drugs were announced. The following table shows GPhA meetings at which Mylan was in attendance, and the dates and locations of these meetings.

<b>Meeting</b>	<b>Meeting Date &amp; Location</b>
2012 GPhA Annual Meeting	February 22-24, 2012 Orlando, Florida
2012 GPhA Fall Technical Conference	October 1-3, 2012 Bethesda, Maryland
2013 GPhA Annual Meeting	February 20-22, 2013 Bethesda, Maryland
2013 GPhA CMC Workshop	June 4-5, 2013 Bethesda, Maryland
2013 GPhA Fall Technical Conference	October 28-30, 2013 Bethesda, Maryland
2014 GPhA Annual Meeting	February 19-21, 2014 Orlando, Florida

421. These in-person meetings provided additional opportunities to collude. As forty-six state attorneys general have now alleged: these trade shows “provide generic drug manufacturers . . . with ample opportunity to meet, discuss, devise, and implement a host of anticompetitive schemes that unreasonably restrain competition[.]”

422. Mylan and other generic drug companies use other industry trade shows and customer conferences to collude, including conferences hosted by the National Association of Chain Drug Stores, Healthcare Distributions Management Association (now known as the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing, among others. The 46 States have alleged further that at these various conferences and trade shows, sales representatives from many generic drug manufacturers . . . have opportunities to interact with each other and discuss their respective business and customers. Attendant with many of these conferences and trade shows are organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities that provide further opportunity to meet with competitors outside of the traditional business setting. Of particular importance here, generic drug manufacturer representatives who attend these functions, . . . use these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers, among other competitively-sensitive information.

423. The 46 States also have alleged that sales representatives of generic drug manufacturers “get together separately, in more limited groups, allowing them to further meet face-to-face with their competitors and discuss their business.” “In fact, high-level executives of many generic drug manufacturers get together periodically for what at least some of them refer to as ‘industry dinners.’” “At these industry dinners, one company is usually responsible for paying for the dinner for all of the attendees. The company that pays the bill is generally determined by alphabetical order.”

## **7. Sufficient Numbers to Drive Competition**

424. While the markets for the Price-Fixed Drugs had a small enough number of competitors to foster collusion, the number of makers was large enough that – given decades of experience with competitive generic pricing, and accepted models of how generic companies vigorously compete on price – one would have expected prices to remain at their historical, near direct cost levels. With the number of generic competitors such as there were here, historical fact and accepted economics teaches that – absent collusion – prices would remain at competitive levels.

## **8. Absence of Departures from the Market**

425. There were no departures from the markets for the Price-Fixed Drugs that could explain the price increases.

## **9. Absence of Non-Conspiring Competitors**

426. Mylan and its co-conspirators have maintained supracompetitive pricing for the Price-Fixed Drugs throughout the Relevant Period. Thus, they have oligopolistic market power in the markets for the Price-Fixed Drugs, enabling price increases without loss of market share to non-conspirators. Indeed, no competitors not part of the conspiracy have emerged to undercut the Mylan and its coconspirators' supracompetitive pricing.

## **10. Size of Price Increases**

427. The magnitude of the price increases involved in this case further differentiates them from parallel price increases. Oligopolists seeking to test market increases need to take measured approaches. But here the increases are not 5% or even 10% jumps—the increases are, in just one act, more than 200 times the current price of the product. A rational oligopolist, when unaided with the certainty that its ostensible competitors would follow, would not do so.

## 11. Reimbursement of Generic Drugs

428. This market, as with many generic markets, has institutional features that would inhibit non-collusive parallel price increases. The reimbursement for generic pharmaceuticals to retail pharmacies is limited by Maximum Allowable Cost (“MAC”) pricing, which is based on the lowest acquisition cost for each generic pharmaceutical paid by retail pharmacies purchasing from a wholesaler for each of a pharmaceutical’s generic equivalent versions. As a result, the usual inhibition of an oligopolist to unilaterally raise prices is embedded in the generic reimbursement system. In the absence of coordinated pricing activity among generic manufacturers, an individual generic manufacturer cannot significantly increase its price without incurring the loss of a significant volume of sales. However, when one observes significant price increases—particularly those of the kind alleged here—basic market economics dictates that the generic drug makers likely had an expectation that they would not lose volume (based on their expectations of what their ostensible competitors would do), because they colluded.

### **J. Mylan Misled Investors about the Competition it Faced and the Validity of its Sales**

429. Mylan repeatedly stated that the generic drug market is highly competitive. Mylan’s statements about the highly competitive nature of the generic drug market were misleading to the extent that Mylan failed to state that the market for generic drugs had been allocated between competitors, and that the prices for drugs had been fixed at supracompetitive levels.

430. Mylan also made numerous statements regarding its sales of drugs and its related financial performance. Mylan’s statements about its sales were misleading to the extent that these figures were based on fixed prices, rather than prices dictated by market forces—investors

believed these figures to be based on Mylan's performance in competitive markets, when in fact they were not.

431. These and Mylan's numerous other misleading statements relating to Mylan's market allocation and price-fixing activity are detailed herein.

**K. The DOJ, SEC, Congress, and Many States Have Responded to the Massive Increases in the Prices of Generic Drugs, Including the Price-Fixed Drugs**

432. Mylan's dramatic and unexplained hikes in the prices of the Price-Fixed Drugs and other drugs have given rise to extensive scrutiny by the United States Congress and by federal and state antitrust regulators.

433. In a January 8, 2014 letter to members of key committees of the United States House of Representatives and Senate, Douglas P. Hoey, Chief Executive Officer of the NCPA, asked Congress to conduct an investigation of generic drug price increases.

434. In July 2014, the attorneys general of twenty states, including the Attorney General of Connecticut, began a wide ranging investigation into the pricing of generic drugs by generic drug companies, including Mylan.

435. On October 2, 2014, Representative Elijah E. Cummings ("Cummings"), the Ranking Member of the House Committee on Oversight and Government Reform and Senator Bernie Sanders ("Sanders"), Chairman of the Subcommittee on Primary Health and Aging of the Senate Committee on Health, Education, Labor and Pensions, sent letters to drug manufacturers, including Mylan, asking for detailed information on the generic price hikes.

436. On November 20, 2014, Senator Bernie Sanders's committee held a hearing entitled "Why Are Some Generic Drugs Skyrocketing in Price?" Various witnesses discussed the price hikes for generic drugs.

437. By November 2014, the DOJ commenced a wide-ranging criminal investigation of generic drug pricing and had caused grand jury subpoenas to be issued to various generic drug manufacturers, including Mylan, in connection with this investigation.

438. On February 24, 2015, Sanders and Cummings wrote a letter to the Office of the Inspector General (“OIG”) of HHS, asking it to investigate the effects that price increases of generic drugs have had on generic drug spending within the Medicare and Medicaid programs. The OIG responded in a letter dated April 13, 2015, saying it planned to engage in a review of quarterly average manufacturer prices for the 200 top generic drugs from 2005 through 2014.

439. In December 2015, the DOJ issued Mylan and certain of its employees and senior management a subpoena relating to the marketing of some of Mylan’s generic products, as well as “any communications with competitors about such products.” Related search warrants also were executed in connection with the DOJ’s investigation. The DOJ probes initially were focused on two generic drugs: digoxin and doxycycline. Recent news reports have confirmed the DOJ’s investigation is significantly broader and encompasses as many as a dozen generic drug manufacturers and is examining a conspiracy to fix, raise, maintain and stabilize the prices of as many as two dozen generic drugs, including the Price-Fixed Drugs. (Moreover, these reports suggest that a leniency applicant came forward during the summer of 2016 and is working with the DOJ in its ongoing investigation.)

440. The DOJ investigation could result in the imposition of substantial fines and criminal pleas for Mylan, and jail time for Mylan executives. Some analysts have estimated that

Mylan could face liability between \$380 million and \$770 million in fines and that the DOJ could impose industry-wide fines in excess of \$1 billion.<sup>42</sup>

441. Also in December 2015, Mylan received a subpoena from the Attorney General of Connecticut regarding the price and marketing of Doxycycline.

442. On December 14, 2016, the attorneys general of twenty states (the “20 States”), including the Attorney General of Connecticut, filed a civil case against six generic drug manufacturers, including Defendant Mylan. The 20 States allege that their investigation, which is still ongoing, “uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States.” The 20 States’ “initial civil action” concerned two generic drugs: Doxycycline Hyclate Delayed Release and Glyburide. The 20 States have made clear that the evidence of wrongdoing they have uncovered extends far beyond the defendants and drugs identified in their “initial civil action.” The Attorney General of Connecticut, George C. Jepson, whose office led the 20 States’ antitrust investigation, told the New York Times: “We believe that this is just the tip of the iceberg. I stress that our investigation is continuing, and it goes way beyond the two drugs in this lawsuit, and it involves many more companies than are in this lawsuit.”

443. Also on December 14, 2016, the DOJ brought felony charges against two former senior generic pharmaceutical executives for their roles in conspiracies to fix prices, rig bids, and allocate customers for generic drugs. The DOJ alleged that Jeffrey Glazer, the former CEO of Heritage, and Jason Malek, the former president of the same company, conspired to fix prices, rig bids, and allocate customers for doxycycline hyclate, an antibiotic. The DOJ also alleged that

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<sup>42</sup> Eric Sandowsky, *DOJ’s Price-Fixing Investigation Could Lead to Sizable Liabilities, Analyst Says*, FiercePharma (Nov. 10, 2016), available at <http://www.fiercepharma.com/pharma/doj-s-price-fixinginvestigation-could-lead-to-sizable-liabilities-analyst-says>.

Glazer and Malik conspired to fix prices and allocate customers for glyburide, a medicine used to treat diabetes. This conspiracy included Mylan executives. The DOJ alleged that the “doxycycline hyclate conspiracy” began in approximately April 2013 and continued until at least December 2015.

444. On January 9, 2017, Glazer and Malik pled guilty to felony charges that they conspired with competitors to manipulate prices and allocate customers for doxycycline. Defendant Glazer admitted *that*:

[He] participated in a conspiracy with other persons and entities engaged in the production and sale of generic pharmaceutical products including Doxycycline Hyclate, the primary purpose of which was to allocate customers, rig bids and fix and maintain prices of Doxycycline Hyclate sold in the United States in furtherance of the conspiracy. Defendant and his co-conspirators, including individuals that the defendant supervised at his company and those he reported to at his company’s parent, engaged in discussions and attended meetings with the co-conspirators involved in the production and sale of Doxycycline Hyclate. During such discussions and meetings, agreements were reached to allocate customers, rig bids and fix and maintain the prices of Doxycycline Hyclate sold in the United States.<sup>43</sup>

Defendant Malik admitted substantially the same facts.<sup>44</sup>

445. On May 10, 2019, the attorneys general of the 46 States filed the Connecticut Teva Action – a new antitrust action against Mylan and other generic drug companies in the U.S. District Court for the District of Connecticut. The Connecticut Teva Complaint alleges an industry-wide conspiracy that included Mylan, in which competitors were expected to receive their “fair share” of the market for a given generic drug and were expected to “play nice in the sandbox” so as not to undercut the other participants in the conspiracy. *Id.* at ¶¶ 130-131. The Connecticut Teva Complaint further alleges that executives at Mylan expressly agreed with other

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<sup>43</sup> Tr. of Plea Hearing at 19:16-20:4, *United States v. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa. Jan. 9, 2017) (ECF No. 24); *see also id.* at 22:4-11 (admitting facts).

<sup>44</sup> Tr. of Plea Hearing at 19:12-20:1, *United States v. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa. Jan. 9, 2017) (ECF No. 24); *see also id.* at 21:23-22:6 (admitting facts).

drug companies in specified calls and other communications to allocate the market for, and to fix the prices of, numerous generic drugs—activity involving virtually the entire generic drug industry.

**V. Throughout the Relevant Period, Defendants Misled Investors about Mylan’s Quality Controls and Operating Capacity**

**A. Defendant Malik Joins Mylan**

446. In the 2000s, Mylan began to expand significantly through acquisitions of India companies, gaining access to the Indian and Chinese markets and acquiring significant manufacturing facilities.

447. In late 2006, Mylan announced its acquisition of Matrix Laboratories (“Matrix”), a publicly traded company based in India that had served as one of Mylan’s major active pharmaceutical ingredient (“API”) suppliers. As part of the transaction, Mylan installed Defendant Malik—Matrix’s then-CEO—as its Executive Vice President for Global Technical Operations.

448. Before joining Matrix, Defendant Malik had spent seventeen years at Ranbaxy, an Indian generic drug manufacturer, where he rose through the ranks to become the Head of both Formulation Development (*i.e.*, research and development) and Regulatory Affairs. During Defendant Malik’s tenure and shortly after he left, Ranbaxy was the site of what Bloomberg later called “one of the most dramatic examples of data manipulation in the history of the generic business.” As Katherine Eban, investigative journalist and author of *Bottle of Lies: The Inside Story of the Generic Drug Boom*,<sup>45</sup> describes, a Ranbaxy employee who worked in data integrity blew the whistle on Ranbaxy after discovering that the company had “lied to regulators, falsified

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<sup>45</sup> Katherine Eban, *Bottle of Lies: The Inside Story of the Generic Drug Boom*, (2019).

data and endangered patient safety.” The Ranbaxy whistleblower discovered that, among other violations, Ranbaxy’s scientists routinely faked dissolution studies and substituted lower-purity ingredients for higher ones to reduce costs. Sometimes, the company simply invented data. As Katherine Eban describes, “There was little effort to conceal this method of doing business. It was common knowledge.” The Ranbaxy whistleblower ultimately resigned and reported his findings to the FDA, which conducted an armed raid on the company’s New Jersey headquarters. While Defendant Malik had left Ranbaxy by the time of the FDA raid, according to *Bottle of Lies*, the practices reported by the whistleblower were widespread throughout Malik’s tenure.

449. As reported in *Bottle of Lies*, Defendant Malik took charge of overseeing Mylan’s “swelling operation in India, where the company would soon grow to have twenty-five of its forty global facilities and over half of its 30,000 employees.” Defendant Malik emphasized competition between Mylan’s research and development teams in Morgantown and India, leading the Company in three years to triple the number of drug applications it submitted to the FDA and to double approvals.

450. Publicly, Defendant Malik described his mission at Mylan as one to ensure that Mylan did not meet the same fate as Ranbaxy, which Defendant Malik later described as “a beautiful story gone sad.” As such, Defendant Malik knew that failure to comply with the CGMP and data integrity regulations governing generic drug manufacturers—as described in more detail below—could expose the Company to highly adverse consequences, as discussed below. Punctilious regulatory compliance and quality control, however, were incompatible with Defendant Malik’s “laser-like focus to bring drugs to market,” and his drive to make Mylan “a hothouse of productivity.”

**B. Quality Control and Data Integrity Were Central to Mylan’s Business**

451. As a generic drug maker, Mylan is required to comply with specific FDA quality control regulations, CGMP, relating to the development and manufacturing of its drugs. Mylan’s business, reputation, and ability to manufacture and sell its drugs depended on its strict compliance with CGMP and data integrity standards. Drug makers must certify compliance with CGMP when seeking approval of new drugs, including generic drugs, and must maintain compliance in order to continue to market and sell them. Indeed, under federal law, a drug is “deemed adulterated,” *i.e.*, its strength, quality, or purity is not as labeled, if “the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice.” 21 U.S.C. § 351(a)(2)(B).

452. The FDA principally relies on these process-based regulations because it cannot test all finished drugs or ingredients distributed in the United States. As FDA guidance explains, the agency views CGMP as the “main regulatory standard for ensuring pharmaceutical quality.” CGMP standards require drug manufacturers to establish strong quality management systems and robust operating procedures, detect and investigate all product quality deviations, and maintain reliable testing laboratories. These requirements are codified, in part, at 21 C.F.R. Pt. 11, 21 C.F.R. §§ 210 and 211, and additional guidance issued by the agency. The regulations are designed to ensure a company’s drug product “meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.” 21 C.F.R. § 210.1.

453. The FDA must also necessarily rely on testing and quality control data generated and furnished by Mylan and other pharmaceutical companies in making important public health

decisions about both proposed new drugs and drugs currently on the market. Accordingly, “data integrity” requirements are a key element of the FDA’s CGMP regulations.

454. The FDA’s data integrity requirements are designed to ensure that testing data is complete, consistent, accurate, and free from potential manipulation. These data integrity regulations require, for example, that drug manufacturers record the results of all mandatory quality testing of both drugs and equipment, “thoroughly investigate[]” any results that fail to “meet any of its specifications,” and compile a record of that investigation. 21 C.F.R. §§ 211.100; 211.192 (“Any unexplained discrepancy . . . or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated”).

455. Moreover, manufacturers must thoroughly document and track all steps they take during production, including all quality testing performed and results obtained. For instance, the FDA requires that “production procedures,” including quality testing, must be written and approved by a managerial “quality unit”; that production procedures “be documented at the time of performance,” including “complete records of all tests performed”; and that “[a]ny deviation from the written procedures shall be recorded and justified.” 21 C.F.R. §§ 211.100, 212.192.

456. The FDA insists on rigorous data integrity requirements because data integrity is essential to ensure that test data is neither lost nor manipulated and, therefore, that drugs are safe and effective. As FDA guidance explains, “Data integrity is critical throughout the CGMP data life cycle, including in the creation, modification, processing, maintenance, archival, retrieval, transmission, and disposition of data after the record’s retention period ends.”

457. The FDA’s core CGMP requirement to “thoroughly investigate” failing or anomalous quality testing results prohibits “testing into compliance.” “Testing into compliance” refers to the improper practice of successively re-testing drug products that have failed analytical

testing and inspection until passing results are obtained, without investigating, or even reporting, the failing results. The FDA has long warned manufacturers that “testing into compliance” is a particularly serious violation of CGMP regulations and the scientific standards essential to ensuring consumer safety.

458. For instance, the agency issued guidance in 2006, explaining that “FDA inspections have revealed that some firms use a strategy of repeated testing until a passing result is obtained, then disregarding the out-of-specification (“OOS”) results without scientific justification. This practice of ‘testing into compliance’ is unscientific and objectionable under CGMPs.” The guidance further lays out strict rules for performing quality testing, “The maximum number of retests to be performed on a sample should be specified in advance in a written standard operating procedure (SOP) . . . . If the results are unsatisfactory at this point, the batch is suspect and must be rejected or held pending further investigation (§ 211.165(f)).” Importantly, “[t]he number of retests should not be adjusted depending on the results obtained.” Finally, “[a]ny deviation from this SOP should be rare and done in accordance with § 211.160(a), which states that any deviations from written specifications, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified. In such cases, before starting additional retesting, a protocol should be prepared (subject to approval by the [management-level quality control unit]) that describes the additional testing to be performed and specifies the scientific and/or technical handling of the data.”

459. Despite the fact that “testing into compliance,” constitutes a serious data integrity violation, as discussed below, it was widespread at Mylan, including at Morgantown, throughout the Relevant Period, even after the FDA explicitly warned Defendants in 2016 that the practice was pervasive at the facility.

### **C. FDA Enforcement of CCGMP and Data Integrity Requirements**

460. The FDA enforces CGMP and data integrity requirements through periodic inspections of drug makers' manufacturing and packaging facilities. At the conclusion of an inspection, the FDA holds a close-out meeting with company management and shares its observations. If the FDA inspectors identify CGMP violations, the FDA will privately provide the drug maker with a form entitled "Inspectional Observations," known as an FDA Form 483. The FDA will issue these Forms 483 when, "in the investigator's 'judgment', conditions or practices observed, indicate that any food, drug, device or cosmetic have been adulterated or are being prepared, packed, or held under conditions whereby they may become adulterated or rendered injurious to health." Generally, the FDA does not publish, or announce the issuance of, Forms 483—only select Forms 483 are posted to the FDA website. Companies have an obligation to respond to the FDA's observations within fifteen business days with a root cause analysis, impact assessment, and a set of corrective and preventative actions.

461. Following an inspection and issuance of a Form 483, the FDA may also issue a warning letter to a drug manufacturer if, among other things, it believes the manufacturer has failed to take adequate corrective action. Unlike Forms 483, the FDA regularly publishes warning letters on its website.

### **D. FDA Regulatory Actions Arising from CGMP and Data Integrity Violations**

462. The FDA has emphasized that companies that violate CGMP and data integrity requirements face severe sanctions. Indeed, FDA guidance explains that "data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees." In particular, the FDA has noted that it "rel[ies] on firms to do the

right thing when [the] FDA is not present,” and data integrity problems “break trust” between an agency and a regulated entity.<sup>46</sup>

463. If the FDA discovers serious, pervasive, and repeat CGMP and data integrity violations, the FDA may order the company in question to take extensive remedial action that could require the company to cease operations, in whole or in part, and implement expensive, time-consuming corrective measures—just like those Mylan was ultimately forced to implement at its Morgantown facility. Regaining the FDA’s trust and remediating data integrity violations is invariably a difficult, time-consuming, and expensive process. Thus, a failure to adhere to the FDA’s data integrity requirement can have serious, potentially crippling, effects on a company’s ability to get its drugs approved and marketed.

464. Mylan itself acknowledged in filings with the SEC that “failure to comply with CGMP” could result in a host of serious regulatory sanctions and harm to Company’s business, including “warning letter[s], fines, penalties, disgorgement, unanticipated compliance expenditures,” product recalls, and even criminal prosecution.

465. Indeed, prior to and during the Relevant Period, several drug manufacturers experienced serious, even fatal, blows to their profitability because of their failure to adhere to CGMP and data integrity requirements, as Mylan was well aware. For instance, as discussed above, Defendant Malik served as the Head of both Pharmaceutical Development and Regulatory Affairs for Ranbaxy, whose serial violations of CGMP and data integrity standards led to the company’s implosion. In 2008, the FDA issued two warning letters to Ranbaxy

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<sup>46</sup> Capt. Sharon K. Pederson (Thoma), PharmD, National Expert of Pharmaceutical Inspections, FDA, Medical Products and Tobacco Program Operations Branch, Data Integrity Issues & Concerns (Feb. 6, 2017).

stemming from whistleblower reports that Ranbaxy fabricated drug test results during Defendant Malik's tenure. The FDA blocked imports from two of its manufacturing facilities as a result.

466. Likewise, in 2014, the FDA prohibited Ranbaxy from manufacturing and distributing APIs from a facility in Toansa, India, where the agency had discovered numerous CGMP and data integrity violations. Most significantly, the FDA discovered evidence that Ranbaxy was "testing into compliance"—again, successively re-testing drug products after they failed analytical testing and inspection until passing results were achieved, without investigating, and sometimes without even reporting, the failing results.

467. As early as 1991, the FDA forced Barr Laboratories to shut down facilities in New York and New Jersey, and recalled drugs manufactured there, after issuing a Form 483 finding that the drug maker was testing into compliance. Specifically, the FDA found that the company had retested failing quality control results but had "no documentation of any meaningful investigation to determine the cause or reason" for many of the process failures observed.

468. More recently, the Delaware Court of Chancery ruled in 2018, and the Delaware Supreme Court subsequently affirmed, that Fresenius Kabi was permitted to terminate a merger agreement with generic drug maker Akorn, Inc. because the latter failed to disclose widespread CGMP and data integrity violations, including alleged instances of "testing into compliance," and failed to take reasonable steps to address the underlying violations. Significantly, the ruling represented the first time a Delaware court had ever found that a "material adverse event" clause in a merger agreement was triggered. In finding that Akorn's CGMP violations were highly material, the Chancery Court emphasized the high cost of the remedial measures necessary to cure such violations, which included halting or reducing drug production, cuts to the company's

drug portfolio, replacing numerous employees in order to “build a culture of compliance,” and delaying product sales.

469. Accordingly, CGMP and data integrity compliance is not only essential to consumer protection, it is highly material to investors.

**E. Prior to the Relevant Period, Price Erosion in Mylan’s Core Generics Business Placed Enormous Pressure on the Company to Sustain Morgantown’s Massive Volume**

470. Prior to the start of the Relevant Period, Mylan began to experience significant price pressures with respect to its core generics business and some of its most lucrative branded products, such as the EpiPen.

471. First, low-quality competitors were entering the marketplace and undercutting Mylan’s generic drug prices and market share. Second, in 2016 and 2017, several of Mylan’s large pharmacy customers began to consolidate into buying consortia with drug manufacturers. This trend placed significant pressure on Mylan to keep its prices low.

472. Analysts recognized the risks to Mylan’s bottom line stemming from price erosion and consolidation among drug companies and pharmacies. As Morningstar’s analyst noted in June 29, 2016, “Mylan faces considerable competition from low-cost producers, especially India-based generic drug manufacturers. Aggressive entry pricing could weaken Mylan’s dominant market position.” An August 9, 2017 Cantor Fitzgerald analyst report described that one of the downside risks facing Mylan was “generic drug pricing continu[ing] to decline. This could come from increasing competition for Mylan’s key products. Also, customer consolidation has given buying consortiums the power to negotiate better prices, and these consortiums could continue to cause prices to fall.” J.P. Morgan wrote in an August 13, 2017 analyst note that, “[W]e remain cautious on the group as elevated levels of competition and

customer consolidation suggest the challenging generic pricing environment could persist for an extended period of time (*i.e.*, through at least 2018).”

473. As discussed in more detail below, in the face of this significant pricing pressure, Mylan dramatically cut corners on CGMP compliance to maximize production and margins at its Morgantown plant.

**F. Defendants Assured Investors that Mylan’s Quality Assurance Processes Were Robust**

474. Recognizing that product quality was of the utmost importance to Mylan’s business, Defendants carefully curated the Company’s public image as a leader in product quality and safety. In this way, Defendants repeatedly highlighted Mylan’s reputation for product quality and compliance as an important differentiator and growth driver.

475. For instance, throughout the Relevant Period, Mylan prominently trumpeted its manufacturing processes on the Company’s website as exceeding applicable product quality standards:

- “*Quality*. Mylan applies one global quality standard across our facilities . . . . Because there’s nothing generic about our standards. Our internal teams conduct reviews of all products, start to finish.”
- “Mylan uses advanced testing and monitoring systems to assure product adheres to testing acceptance criteria that are in alignment with requirements established by standard-setting organizations around the world.”
- “*Advanced Monitoring Systems*. Although not required, Mylan utilizes state-of-the-art monitoring systems that can automatically evaluate and reject a product that does not meet specifications. This advanced technology is used to automatically remove a defective product from production or packaging lines.”
- “*One Global Quality Standard*. Whether it’s a medication for millions or for a handful of people, our priorities are to meet or exceed industry standards. Our own teams conduct ongoing reviews to ensure quality and integrity of products, start to finish, and to continually improve for optimal quality and consistency.”

*“Proof of Purity and Potency.* Mylan assures product potency, purity and drug release through expiration date by testing the stability of our products at specific intervals.”

In SEC filings and at investor conferences, Mylan repeatedly encouraged investors to visit its website to understand its business.

476. Likewise, during the Relevant Period, Mylan filed its Annual Report with the SEC on Form 10-K, in which it highlighted Morgantown as a “significant” manufacturing facility. Mylan stated, “We believe that all of our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for the current operations.” Similarly, in the Company’s May 2017 proxy statement issued to investors, Defendants stated that Mylan’s key “strengths” included its “[p]owerful, high quality manufacturing platform.” Specifically, Defendants stated that “[o]ur 50 plants around the world manufacture tens of billions of doses of medicine annually, and each site adheres to stringent quality standards, regardless of location.”

477. Likewise, on Mylan’s May 10, 2017 first quarter earnings call, Defendant Malik reassured investors about the warning letter, stating that “Mylan has always had a deep and unwavering commitment to quality everywhere we operate,” that Mylan was “dedicated to continually enhancing our systems and processes, with a deliberate and thorough approach to ensure sustainable quality across our entire network of facilities.” Defendant Malik further stated that “[p]roduction from Nashik site continues uninterrupted, and we anticipate no material impact to Mylan’s overall business as a result of this warning letter.”

478. Given Mylan’s carefully crafted public image as an exemplar of “stringent” product quality standards, investors credited Defendants’ soothing statements. For instance, in a May 10, 2017 report, BMO analysts reported that the issues identified were well on their way to remediation. Likewise, Susquehanna analysts issued a May 11, 2017 report crediting Mylan’s

“affirm[ation] that it doesn't expect a material impact from the warning letter on the Nashik, Indian manufacturing plant.”

479. Unbeknownst to investors, these same CGMP failures were widespread throughout Mylan's facilities, including its critical Morgantown plant—the cornerstone of its U.S. operations. In fact, Mylan had already received the thorough and scathing 2016 Form 483 concerning the Morgantown facility. However, Defendant Malik failed to disclose the 2016 Form 483, the financial and regulatory risk it entailed, or the costly measures the Company would have to implement to address the violations the FDA discovered.

480. Instead, Defendants held the Morgantown facility up to the market as an exemplar of the Company's rigorous quality control standards. For instance, in October 2017, Defendant Bresch led a tour of the facility for journalists specifically to emphasize Morgantown's purportedly high-quality standards. As West Virginia's State Journal reported on October 23, 2017, Defendant Bresch told reporters that “[q]uality is not a department here”—instead, it was Mylan's whole corporate philosophy. Specifically, based on Defendant Bresch's statements during the tour, the article reported:

Bresch said Mylan prides itself on cleanliness and quality control. “Quality is not a department here,” she said from the company board room following a tour of the plant. For Mylan, quality control is a corporate philosophy. And it begins before the first chemical is mixed. Technicians hand-wash each and every barrel of raw material before it goes into Mylan's warehouse. Containers of ingredients for making pills are transferred from wooden pallets to plastic skids, which are also painstakingly cleaned. Samples of each ingredient are tested to make certain they are what they are said to be. Similar testing goes on during all aspects of tablet and capsule production.

481. Throughout the remainder of the Relevant Period, Defendants continued to assure investors that Mylan adhered to the highest manufacturing standards and touted the Company's robust quality controls. For instance, in an annual governance report issued to shareholders in

June 2017, Mylan told the market that it had “invested significant resources to ensure quality throughout our value chain. Each of its steps is wrapped in a series of reviews designed to meet or exceed the many regulatory and compliance standards enforced by the dozens of health authorities around the globe that regularly inspect us.”

482. And in the Company’s May 2018 governance report, Defendants continued to tout Mylan’s rigorous quality control processes and “extensive, formal internal-audit program.” In that report, Defendants stated, for instance, “Mylan has global systems and processes in place to provide our people with the foundation and tools needed to maintain an effective quality management system . . . . Our Quality Council program provides management with clear, quantitative data, including that of key performance indicators. It also tracks and analyzes quality trends, reviews inspection results and identifies potential areas for employee training.”

483. As discussed below, Defendants failed to disclose that, among other things, by April 2018, the FDA had again concluded that Mylan’s Quality Council had failed to appropriately apply and enforce CGMP and data integrity standards at the Morgantown facility.

484. Analysts credited these claims. For example, throughout the Relevant Period, Susquehanna consistently noted Mylan’s “global quality standard” as a key characteristic of the Company. Similarly, BTIG described in an October 9, 2016 report Mylan’s “Critical Mass with High Quality Manufacturing Capabilities Globally,” observing that, “[o]ver the years, Mylan has built a strong reputation as a quality drug manufacturer.”

**G. Defendants Touted Mylan’s “Broad” Operating Capacity and Assured Investors that the Company Did Not Need to Downsize its Generics Portfolio**

485. During the Relevant Period, Defendants also made materially false and misleading statements touting the Company’s “broad” operating capacity, specifically its ability

to manufacture a huge volume of a broad range of drugs. In addition, Defendants assured the market that the Company did not need to downsize its generics portfolio, even as Defendants knew that its flagship Morgantown facility would have to dramatically reduce its output in order to meet its regulatory obligations. And, as set forth above, Mylan told investors that it was “able to manufacture tens of billions of doses of medicine annually, all to stringent quality standards.”

486. These statements were a key selling point for the Company. For example, at the June 2016 Goldman Sachs Healthcare Conference, Defendant Bresch told investors that Mylan’s operating capacity gave the Company a significant competitive advantage in attracting and retaining customers: “It’s always been a volume-driven business, always . . . [T]here’s a much—more of a sense from our customer base that having a reliable global supply chain is important, that they don’t want to have to turn customers away because of products—they’re not able to get their hands on a product.” Similarly, at a January 2018 J.P. Morgan Healthcare Conference, Defendant Bresch claimed that “where Mylan has differentiated itself is, one, having that broad base, that portfolio, the capacity to truly meet the supply that’s needed . . . . And all of that gives us a seat at the table perhaps a bit differently than our peers.”

487. Defendants also stated that the Company’s vast operating capacity not only allowed it to negotiate favorable prices with its customers, but also to quickly enter markets affected by shortages and capture favorable pricing. Further, Defendants repeatedly denied that Mylan needed to cede this advantage and “rationalize” its portfolio. For example, at the January 2018 J.P. Morgan investor conference discussed above, an analyst asked whether Mylan needed to reduce its generics portfolio in order to limit its exposure to “loss-making products.” Defendant Bresch, specifically referencing the Morgantown facility touted the fact that Mylan was “running facilities that are making 15 billion tablets and capsules in a year.” Defendant

Bresch explained that “you could be making less money on one day, you could be making more on the next, given the dynamics in the supply chain. So, for us, as others are having financial constraints or having to make perhaps short-term decisions because they have to, I think we have found ourselves in a position to really take into consideration again that long-term view.” At that same conference, Defendant Bresch later emphasized this point: “[A]s other companies are forced to rationalize [Mylan is] able to absorb those different volumes is what we’ve really been set up to do.”

**H. In Truth, Mylan’s Manufacturing Facilities, Including its Key Morgantown Plant, Were Rife with Serious CGMP and Data Integrity Failures**

488. In truth, and unbeknownst to investors, Mylan’s manufacturing facilities, including its flagship Morgantown facility, were rife with systemic, egregious, and long-standing CGMP and data integrity failures. These failures exposed the Company to serious regulatory penalties, costly disruptions, and expensive remediation. Far from “conduct[ing] reviews of all products, start to finish” and “us[ing] advanced testing and monitoring systems to assure product adheres to testing acceptance criteria,” Mylan failed to perform quality assurance testing on the vast majority of the products manufactured at Morgantown. When testing did occur, Mylan routinely engaged in improper “testing into compliance” by repeatedly re-testing drug products after they failed inspection until passing results were achieved without investigating the failing results. Mylan systematically misstated investigative findings, altered drug samples, “improperly invalidated” reports of defects, and engaged in suspect data practices designed to avoid recording failing quality testing results on internal systems, including by crashing them.

489. Moreover, contrary to Defendants’ statements touting Mylan’s “broad” operating capacity and assuring investors that the Company did not need to “rationalize” its generics

portfolio, Defendants knew, and admitted in private correspondence with the FDA, that “the large volume of doses and products within the Morgantown portfolio . . . inhibited [Mylan’s] ability to achieve the high level of control over our manufacturing processes that we expect.” As former Mylan employees explained, and as the Company itself acknowledged, Mylan failed to perform the rigorous quality testing it assured investors it was performing on “all products, start to finish” because the Company’s single-minded focus on production volume made doing so impossible. Accordingly, Mylan was ultimately forced to halt production at Morgantown and reduce the facility’s generics portfolio by nearly two thirds.

490. As discussed further below, Defendants received numerous warnings of Mylan’s widespread and serious CGMP and data integrity failures, including scathing non-public reports directly from the FDA detailing these practices at several Mylan facilities, including Morgantown. Mylan also participated in private meetings with the agency to discuss these findings and was forced to recall numerous products tied to Morgantown. Yet, astonishingly, Defendants still failed to address Mylan’s profound consumer safety failures and the gaping holes in its CGMP compliance, even as they touted the Company’s quality assurance processes and operating platform to investors.

**1. Prior to the Start of the Relevant Period, Defendants Received Numerous Warnings of CGMP and Data Integrity Failures at Mylan, Including at Morgantown**

491. As *Bottle of Lies* later revealed in 2019,<sup>47</sup> a Mylan whistleblower traveled to the FDA’s Maryland headquarters in mid-2015 and reported that “under Rajiv Malik’s leadership,” Mylan’s research and development center in Hyderabad “had become a hub for data fraud that had disseminated its methods of falsification throughout Mylan’s Indian operations.” The

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<sup>47</sup> Katherine Eban, *Bottle of Lies: The Inside Story of the Generic Drug Boom*, (2019).

whistleblower further reported that the masterminds of the data fraud techniques “held key leadership positions at Mylan” and included former Ranbaxy employees. As Bloomberg reported in January 2019, the whistleblower raised concerns about CGMP and data integrity violations at Morgantown, reporting “unscrupulous activity at the factory where the generic giant makes some of its top-selling drugs.”

492. Among other things, the whistleblower reported that in order to generate passing product quality testing results, commercial samples of specific drugs bound for the U.S. market had been switched with more stable pilot samples. In addition, the whistleblower reported that Mylan was not only “testing into compliance,” but it also had developed a novel method for hiding the fact that the Company was repeatedly re-testing failing samples until passing results were obtained. Instead of deleting or altering failing test results, which would have left a trail of metadata for FDA investigators, plant managers deliberately corrupted data files and crashed computers when the instruments used for quality analysis began to indicate that an out-of-specification (“OOS”) result was inevitable. According to the whistleblower, Defendant Malik’s team had instructed Mylan personnel that this was a better way to evade investigators.

493. Former Mylan employees echoed the FDA whistleblower’s report. For instance, *Bottle of Lies* recounts an interview with a former Mylan chemist who described how Mylan had moved dozens of generic drug applications swiftly through the system, using “cooked” data at each step of the manufacturing process. According to the Mylan chemist, this manipulation occurred under the leadership of Defendant Malik and his team. The Mylan chemist stated that Defendant Malik’s team used an array of deceptive methods to hasten approval of critical products. For instance, the chemist reported that Mylan generated bioequivalence data by switching drug samples, using hidden equipment to tinker with secret substitutions.

494. Defendant Malik also deployed research and development teams to different sites to manage failing data. The Mylan chemist reported that when commercial drug batches, like those manufactured at Morgantown, failed on stability, “[y]ou play with the parameters so impurities don’t show up.” At each step, “people come from [research and development] to show how to fix the issue.” Based on his objections to the data manipulation he witnessed, the Mylan chemist resigned and, shortly thereafter, “detailed his allegations in writing to senior managers.”

495. FDA memoranda (which Katherine Eban reviewed) demonstrate that the agency found the whistleblower’s claims credible. However, the agency was apparently reluctant to strike at the heart of Mylan’s operations.

496. In 2016, the whistleblower privately sent the FDA a follow-up email that jolted the agency out of inaction. The whistleblower warned the FDA that its inaction could harm American patients: “Perhaps the agency awaits a definitive tragedy to occur on U.S. soil due to substandard generic drug products not meeting the safety & efficacy standards.” The whistleblower continued, “Honestly—I had supreme faith & trust in the agency’s approach—towards bringing those to justice who commit fraud.”

## 2. The Nashik Form 483

497. As Katherine Eban reported in *Bottle of Lies*, the whistleblower’s admonishment set off a scramble inside the FDA. Approximately two months later, on September 5, 2016, the FDA arrived at Mylan’s Nashik, India facility to conduct a surprise inspection. Throughout their nine-day inspection of the Nashik plant, FDA investigators found evidence strongly corroborating the whistleblower’s report. As a result, the FDA privately issued a lengthy Form 483 to the Company (the “Nashik Form 483”).

498. The Nashik Form 483 shows that, as the whistleblower reported, failing or OOS results “were invalidated without sound scientific justification.” Instead, Mylan either conducted no investigation into the cause of the failures or invalidated them for clearly pretextual reasons.

499. Indeed, investigators found that the plant’s software had recorded scores of error messages showing “instrument malfunction,” “power loss,” and “connection to chromatography system lost.” Significantly, plant managers had apparently conducted no investigation into the repeated crashes. Instead, Mylan re-tested the drugs after receiving the error messages, indicating that computers had been suddenly shut down in the midst of analyses in order to avoid recording failing results and facilitate re-testing—*i.e.*, “test into compliance”—just as the whistleblower had reported. This technique was so notable that the FDA gave it a nickname: “crashing files.”

500. The FDA investigators also found that “[e]quipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product.”

### **3. The FDA’s Surprise Inspection of Morgantown in 2016**

501. Less than two months later, on November 7, 2016, and unbeknownst to investors, three international FDA investigators, including the investigator who had conducted the Nashik inspection, arrived unannounced at Mylan’s Morgantown facility. According to the Amended Complaint in the W.D. Pa. Mylan Class Action, Former Employees<sup>48</sup> provided reports confirming that the FDA’s Surprise Inspection was of the utmost seriousness. For example, FE1 worked at Morgantown for years prior to the start of the Relevant Period until May 2017 and held positions in Quality Control and as a Technical Area Lead in Packaging during the Relevant

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<sup>48</sup> References herein to “Former Employees” and/or “FEs” are to the former Mylan employees whose reports are discussed in the Amended Complaint in the W.D. Pa. Mylan Class Action.

Period. As FE1 reported, a surprise FDA inspection of Morgantown was highly unusual. Typically, Mylan scheduled inspections of Morgantown in advance, agreeing with inspectors from the local FDA office on a mutually convenient date.

502. As Katherine Eban reported in 2019 in *Bottles of Lies*, the international FDA investigators who visited Morgantown in November 2016 were “stunned” to discover a host of egregious violations of core CGMP and data integrity regulations, including testing into compliance and other “suspect data practices.” Indeed, the volume and severity of Mylan’s improper practices forced the FDA to add a fourth international inspector to join the team.

503. Unbeknownst to investors, on November 18, 2016, following the surprise inspection, the FDA privately issued a lengthy Form 483 addressed to Mylan’s Head of Global Quality Operations, Reem Malki. In the 2016 Form 483, investigators reported that they observed numerous instances of “testing into compliance” involving several different drugs, including drugs Mylan would later be forced to recall.

504. Specifically, the 2016 Form 483 stated that while testing of these drug batches had yielded “out-of-specification (‘OOS’), out-of-trend (‘OOT’) and other anomalous results, [they] were retested without any investigation” into the causes of the failing or anomalous results until passing results were obtained and were then “released” to the American public. As discussed above, successive retesting of failing quality and safety results, without conducting a CGMPmandated investigation into the cause of the failure, strongly indicates the batches, equipment, or analyses were manipulated simply to achieve passing results and to avoid costly production delays or product recalls. Moreover, Mylan’s practice of testing into compliance was directly contrary to Defendants’ public statements, including that the Company “conduct[ed]

reviews of all products, start to finish” and “uses advanced testing and monitoring systems to assure product adheres to testing acceptance criteria.”

505. In other cases, investigators discovered that failing test results had been invalidated for apparently pretextual reasons. Once again, tests were then re-run until Mylan obtained passing results. For instance, the 2016 Form 483 noted that several Mylan Trending Assessment reports showed that failing test results were chronically attributed to dirty glassware. “This attribution of OOS results to glassware contamination has been a continued practice at your firm with no effective resolution, and is utilized to invalidate failing results.” Accordingly, investigators’ findings made clear that one of two things was occurring: either the flagship plant of one the most experienced and sophisticated drug manufacturers in the world was suddenly struggling to clean its glassware and was doing little to address the problem, or Mylan was not being truthful about the reasons it was invalidating failing results.

506. Indeed, the FDA observed that, in some cases, the analysts either did not report the initial failure at all, or misreported the data relating to it. The FDA also pointed out that despite “the mishandling of analytical data by these analysts,” Mylan’s Director of Analytical Investigations acknowledged that “no assessment of the analyst’s previous and other work had been conducted.” Mylan’s failure to assess the analyst’s previous work contravened data integrity standards.

507. Likewise, FDA investigators discovered that technicians had been pre-injecting drug samples into gas chromatographs “prior to official analyses,” apparently to preview the test results and avoid recording an official failure. While Mylan executives on the Company’s Quality Unit later told FDA investigators that the injections were done for purposes of instrument setup, the FDA noted that the data did not appear to support that explanation. First,

the names assigned to these analyses in Mylan’s systems appeared either designed to obscure their purpose or confirmed that they were trial or test injections, including names like “TEST,” “Besylate ID,” “lop,” “0,” and “New MP test injects LMFAO”—a popular acronym for “laughing my f--- a-- off,” suggesting the analyst was “laughing” at the notion that the injections were “new.” Second, the FDA pointed out that the “area values”—the output—of the suspect analyses “are similar to standards and samples run during the official analyses,” indicating that analysts were actually attempting to preview test results for batch samples, not setting up their instruments.

508. Moreover, and consistent with the conclusion that Mylan was “testing into compliance,” the FDA also found that Mylan had significantly altered drug sample sets—including changes to sample weight, composite weight, and dilution factor—and no investigation had been conducted to determine whether changes were made for valid reasons. Notably, the FDA found that this improper practice had occurred in connection with valsartan, a drug that Mylan would later recall because it had been contaminated with known carcinogens.

509. Also consistent with these suspect data practices, the FDA found bins full of shredded data and quality control records in Morgantown’s Quality Control, Quality Assurance, and Packaging areas—areas where, pursuant to CGMP requirements, every piece of paper is supposed to be saved.

510. In addition, the FDA found that Mylan failed to contemporaneously validate that the test methods supposedly used to certify drug products, including APIs, met specification. The FDA cited numerous instances in which validation of stability testing occurred months or even years after quality testing was supposedly performed.

511. The FDA further pointed out that Mylan “manufacture[d] drug products despite an awareness of manufacturing investigation reports and complaints related to known repeated manufacturing deficiencies,” including by “inappropriately” invalidating consumer complaints.

512. Accordingly, the FDA concluded, among other things, that Mylan’s Morgantown plant failed to meet core CGMP and data integrity requirements. The FDA concluded that Mylan’s “[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity,” as required by 21 C.F.R. § 211.160; and “[t]here is a failure to thoroughly review any unexplained discrepancy [between quality test results and required product standards] whether or not the batch has already been distributed,” as required by 21 C.F.R. § 211.192. The FDA classified the Morgantown inspection as “Official Action Indicated,” the most serious classification in the agency’s inspection rating system, which, the FDA explains, “means regulatory and/or administrative actions will be recommended.” In other words, Mylan was warned that the violations were of the utmost seriousness and that investigators would recommend the Company receive additional regulatory sanctions.

513. The FDA did not publicly disclose the 2016 Form 483. Defendants continued to issue misstatements touting Mylan’s supposed adherence to strict quality control measures and its rigorous and robust quality assurance processes.

#### **4. Mylan Former Employees Corroborate the FDA’s Findings**

514. As discussed above, the Amended Complaint in the W.D. Pa. Mylan Class Action pleads that former Mylan quality personnel confirmed the FDA’s findings of egregious and systemic CGMP and data integrity violations at Morgantown and other Mylan facilities. That

Amended Complaint asserts that, just as the FDA privately warned Mylan in its 2016 Form 483, Former Employees have confirmed that these violations were widespread throughout Morgantown long before the FDA’s November 2016 inspection and were known to senior management.

515. First, Mylan’s Former Employees confirmed that “testing into compliance” was a bedrock practice at Morgantown from before Relevant Period and throughout—continuing even after the 2016 Form 283 was issued, as the FDA later confirmed. For example, as discussed above, the Amended Complaint references FE1, who worked at Morgantown for years prior to the start of the Relevant Period until May 2017 and held positions in Quality Control and as a Technical Area Lead in Packaging during the Relevant Period. FE1 echoed the FDA’s findings that the practice of retesting OOS drug products and equipment until passing results were obtained was widespread at Morgantown for years prior to the start of the Relevant Period and throughout the remainder of FE1’s tenure at the Company. FE1 stated: “the FDA calls that ‘testing into compliance.’” FE1 stated that Mylan “never looked into why we are having failures and how can we avoid them in the future . . . instead of investigating, they said we need to get this batch out.” FE1 explained that batches with failing results should be flagged and held until an appropriate root cause analysis determines the reason for failure, “but I can’t ever remember doing that at Mylan.”

516. FE1 also reported these issues to senior Mylan executives. FE1 flagged both (i) Morgantown’s failure to test the vast majority of its manufactured drugs and equipment (discussed below) and (ii) its widespread “testing into compliance” to senior Mylan executives, including Kim Kupec, Head of Quality at Morgantown, and Eddie Koski, Senior Director of

Quality Assurance Operations, in meetings in 2015 and 2016, prior to the FDA’s issuance of the Form 483, but FE1’s concerns were ignored.

517. FE2, who, according to the Amended Complaint in the W.D. Pa. Mylan Class Action was a Quality Assurance Specialist at Morgantown from prior to the start of the Relevant Period until April 2018, likewise reported that Mylan “100%” tested into compliance at Morgantown and, indeed, the practice was widespread throughout FE2’s tenure at Mylan. FE2, who was responsible for analyzing drugs and equipment for compliance with quality standards, stated that at the express direction of Quality Assurance supervisors, FE2 and other technicians would retest samples yielding OOS or anomalous results until they passed, without any investigation into the failing results. FE2 stated that Quality Assurance supervisors instructed technicians to “just run it until it passes.” FE2 stated that “testing into compliance,” as directed by Quality Assurance supervisors, continued unabated throughout FE2’s tenure at Morgantown.

518. FE3, who, according to the Amended Complaint in the W.D. Pa. Mylan Class Action was a chemist responsible for quality control and validation at Morgantown from 2016 to 2019, similarly confirmed that throughout FE3’s tenure until at least the FDA issued its 2018 Form 483 (discussed below), failing results were routinely retested until passing results were obtained without any investigation or root cause analysis. Indeed, FE3 reported that Morgantown analysts would “test into compliance” using serial retesting to artificially shift entire trends. As FE3 explained, “If you take something that’s out of trend and test it enough, that becomes the trend.” Moreover, FE3 echoed the FDA’s findings, stating that analysts cited “dirty glassware” or “analyst error” as stock justifications for invalidating results where the cause of the failure could not otherwise be identified.

519. Likewise, FE4, who, according to the Amended Complaint in the W.D. Pa. Mylan Class Action was a quality control chemist at Morgantown from prior to the start of the Relevant Period until mid-2016, reported that “testing into compliance”—which FE4 described as repeating testing until you “miraculously” get the results you need to pass—was “commonplace” at the facility throughout FE4’s tenure. According to FE4, Morgantown personnel lacked the time and resources to meaningfully investigate failing quality tests because Morgantown’s volume was so overwhelming.

520. FE4 reported that, in FE4’s experience, “testing into compliance” occurred most frequently in connection with product “stability testing,” which determines whether a product maintains its strength, purity, and integrity throughout its shelf life. A failing result would have to be promptly reported to the FDA and would trigger a recall. FE4 reported that when test results exceeded the threshold for a recall, they would be rerun multiple times, until the analysts obtained a result just under the recall threshold. All the preceding failing results would then be attributed to stock justifications, most commonly, “analyst error” or “dirty glassware.” Importantly, quality assurance management instructed analysts that when the raw data showed results exceeding the recall threshold, those data should not be “processed” because doing so would start the “clock running” for notifying the FDA. Instead, the analysts were told to meet with quality managers in order to come up with a “game plan” for re-testing the drugs.

521. FE5, who, according to the Amended Complaint in the W.D. Pa. Mylan Class Action was a Quality Compliance Manager from prior to the start of the Relevant Period to November 2016, also reported that failing results were re-tested without adequate investigation at numerous Mylan sites, including Morgantown, Nashik, and Bangalore, throughout FE5’s tenure at Mylan. Among other things, FE5 echoed that Morgantown personnel improperly used

boilerplate justifications for invalidating failing results. The Company's failure to develop corrective and preventative actions in response to the trend of such events demonstrated that the justifications were pretextual.

522. Second, Mylan's Former Employees further echoed the FDA's findings concerning a host of additional suspect data practices and reported that they were in use well before the FDA discovered them during the November 2016 inspection. For instance, the Former Employees reported that, as the FDA concluded in 2016, the Morgantown facility consistently "pre-injected" drug samples to avoid recording bad results. FE1 stated that, prior to the 2016 Form 483, it was a widespread practice at Morgantown to improperly re-inject drug samples into gas chromatographs prior to official analyses. After the issuance of the 2016 Form 483, Mylan continued the practice, but "it became more covert." FE1 stated that analysts "would inject chromatograph and if it came out wrong, out of spec or whatever, it was common practice to just rerun the test."

523. FE4 also reported that, during FE4's tenure, Morgantown personnel pre-injected samples in connection with a variety of different tests, including stability and production testing, to "see where the numbers were."

524. Similarly, Mylan's Former Employees confirmed the FDA's findings that the Morgantown facility engaged in the improper practice that the FDA dubbed "crashing files." FE1 stated that when computers showed analyses were failing, power to the instruments was cut or the computers were crashed to avoid recording a failing result. For instance, FE1 explained that Morgantown's tablet presses had computers that would monitor tablets to ensure they met specifications. If tablets were out of specification, an alert would trigger a "red screen" on the machine's monitor. CGMP standards required Mylan to open an investigation when this

occurred but doing so would-be time consuming and would halt production for up to an hour. To avoid this, employees would shut down the machine. Once rebooted, the OOS result would not be recorded; the instrument would only log “down time” or “loss of power.” FE2 likewise reported that FE2 and other technicians received instructions from Quality Assurance supervisors to abort analyses, *e.g.*, dissolution tests, when testing indicated an OOS result was imminent.

525. Notably, Defendants had previously been warned that the practice of “crashing files” was widespread at Morgantown. As described above, in 2009, Mylan sued the Pittsburgh Post-Gazette after the newspaper reported that, at Morgantown, plant employees regularly “crashed files” (among other unscrupulous tactics) to evade FDA regulations. In response, Mylan not only vigorously and falsely denied the newspaper’s allegations, but also sued the Post-Gazette for misappropriation of trade secrets and libel. In its complaint, Mylan claimed that the newspaper’s reporting would “adversely affect” its business reputation; “impugn the integrity” of its procedures and personnel; and “threaten [its] current and prospective business relationships.” The Company further asserted that the publicization of the Post-Gazette’s allegations “caused harm to Mylan and its shareholders, evidenced by substantial market volatility, a decrease in its stock price, and the resulting decrease in market capitalization.”

526. Third, Mylan’s Former Employees confirmed that Morgantown analysts manipulated test reports. FE1 reported that Morgantown analysts routinely failed to record results and observations contemporaneously, altered reported results to meet specifications, and certified analyses had been performed when they had not. As an example, FE1 explained, if “you get 10.1 and your spec is not supposed to be above 10, I saw people scratch out the .1 and add two 0’s so you get 10.00.” Former Employees also reported being asked to falsify evidence of CGMP remediation. For instance, FE5 traveled to Bangalore to prepare for an upcoming FDA

inspection. Mylan’s Associate Director of Global Compliance instructed FE5 to falsely certify that certain training had been completed, that certain operational guidelines had been issued, and that other CGMP failures had been addressed.

527. Fourth, directly contrary to Defendants’ statements that Mylan “conduct[ed] reviews of all products, start to finish,” Mylan in fact quality tested only a tiny fraction of the drugs manufactured at the Morgantown facility. FE1 reported that, beginning in the late 2000’s and through the remainder of FE1’s tenure, Mylan performed product quality testing on no more than 5% of the drugs manufactured at Morgantown because production demands made broader testing impossible. Notably, FE1 reported that before Morgantown dramatically scaled back its testing in the late 2000’s, shortly after Defendant Malik’s arrival at the Company, Mylan had performed quality testing on every drug manufactured at the facility.

528. Corroborating FE1’s report, FE3 stated that only 3% to 5% of the drugs manufactured at Morgantown were actually subject to product quality testing during FE3’s tenure because the enormous production volume flowing through the facility made more comprehensive testing impossible. According to FE3, Morgantown’s testing covered a “shockingly low percentage” of the drug manufactured at the facility. FE3 explained, “I would see the numbers and think ‘If we’re failing at this [low testing rate], what does that mean for other products?’”

529. Notably, in a private May 2018 letter to the FDA, Mylan acknowledged that it previously failed to perform “quality risk assessments” on “all products manufactured at Morgantown.”

530. FE1 likewise reported that quality testing of the equipment used to manufacture drugs was extremely limited for years prior to the start of the Relevant Period and throughout the

remainder of FE1’s tenure. In many cases, that equipment was swabbed no more than once a year, and, predictably, the equipment would pass only after repeated retesting, while, again, analysts failed to investigate the failing results. “A lot of times we’d swab one piece of equipment one time in a year. Then at end of the year, you would say [to analysts and manufacturing personnel] you only did it once, but they’d say, that’s okay, it passed. But it only passed because it passed the fourth time after failing three times.”

531. Even with the facility’s minimal testing, FE1 reported that as of July 2016, a few months prior to the FDA’s 2016 inspection, Morgantown had a three-month backlog of open and unresolved investigations for product quality failures, which FE1 was responsible for helping to close out. Mylan was thus not only failing to test the vast majority of its drugs for adulteration, it was also failing to timely investigate and resolve known quality deficiencies, just as the FDA’s investigation made clear. FE1 explained that the Company’s failure to timely resolve these investigations violated Mylan’s own operating procedures, which required the Company to resolve investigations within 30 days or, in some cases, 45 days. FE1 reported that the backlog of open investigations was logged into the Company’s incident report tracking system, called TrackWise.

532. Fifth, FE1 echoed the FDA’s findings that the senior leadership of Mylan’s Quality function failed to perform oversight duties mandated by Mylan’s operating procedures. For instance, as the 2016 Form 483 explains, Mylan’s operating procedures tasked Morgantown’s Trending Review Board, comprised of “site senior leadership,” including the directors of the different departments, with evaluating and remediating repeat quality failures. FE1 reported, however, that in 2016, the Trending Review Board simply stopped performing its function. As discussed above and below, FDA investigators arrived at the same conclusion.

533. Sixth, FE1 further reported numerous instances of cross-contamination at Morgantown, in which drugs were contaminated with residue from drugs previously manufactured on the same equipment. In some instances, drug batches contained whole or broken tablets of foreign drugs. These cross-contamination events were logged into the Company's incident report tracking system, called TrackWise, and the data showed a significant trend of these events. According to FE1, these cross-contamination issues represented serious CGMP violations. Employees repeatedly raised these issues with senior Quality personnel, but the senior personnel failed to implement any meaningful remedial measures. Instead, management implemented "band-aid" fixes, such as patching holes and crevices in equipment in an ad-hoc fashion.

534. FE3 also reported that the numerous cleaning validation CGMP violations identified by the FDA in both 2016 and later in 2018, including high swab failure rates for crosscontamination risk, persisted throughout FE3's tenure until at least after the FDA's 2018 Form 483. FE3 stated that because Mylan failed to test the vast majority of the drug products manufactured at Morgantown, numerous rooms within the facility were visibly cross-contaminated, as the FDA observed in both 2016 and 2018. FE3 stated that this was "a huge product and consumer safety issue," as the FDA pointed out, because drugs manufactured in those rooms could contain traces of other drugs or foreign material to which a patient might react adversely. In fact, as discussed above, the FDA cited numerous examples of cross-contaminated drugs manufactured at Morgantown. Moreover, FE3 confirmed the FDA's findings that failing results showing crosscontamination risk were invalidated and retested if a re-swab in another location of the equipment yielded passing results, and that this practice occurred throughout FE3's tenure at Morgantown at least until April 2018. In other instances, failing swab results

were invalidated without any retesting. Indeed, FE3 reported that analysts were discouraged from thoroughly swabbing rooms because any “extra” swabs could turn up evidence of contamination and yield failing results, triggering a time-consuming investigation.

535. Mylan senior management was well aware of these egregious violations of FDA regulations. FE1 corroborated reports from both the 2015 FDA whistleblower and the Mylan chemist that Defendant Malik’s team visited Mylan’s plants, including Morgantown, to coach personnel on data fraud techniques, particularly when new products were being scaled up for commercialization. For instance, FE1 explained that when Morgantown first started making divalproex (prior to the start of the Relevant Period), a seizure treatment, the FDA asked Mylan to make 100 batches and send it to the agency for testing. Defendant Malik’s team came to the facility to oversee the process and, when batches failed quality testing, they instructed employees to destroy the batch and create a replacement, thus concealing the product failure from the FDA.

##### **5. The Morgantown Facility’s Enormous Volume Drove Mylan’s Violations of CGMP Standards**

536. According to the Amended Complaint in the W.D. Pa. Mylan Class Action, Mylan’s Former Employees reported that Morgantown’s severe CGMP and data integrity issues were a direct result of the unrealistic production demands Mylan’s leadership placed on the facility. These production demands strained the site’s manufacturing capacity past its breaking point and made compliance with the most fundamental product quality requirements impossible. While Mylan eventually admitted that its exclusive focus on volume had undermined compliance with CGMP regulations, Former Employees report that this overwhelming strain was known internally at Mylan throughout the Relevant Period. For example, FE6 who, according to the Amended Complaint in the W.D. Pa. Mylan Class Action was a Lead Financial Analyst at Mylan

from prior to the Relevant Period to spring 2018, was assigned to Morgantown and helped oversee the site operations budget, with significant work on the Company's quality budget. Among others, FE6 supported the Vice President and Site Head of Quality at Morgantown. FE6 reported that even prior to the start of the Relevant Period, senior Mylan executives knew and routinely discussed that it was impossible for Morgantown to both meet the facility's outsized production demands and satisfy its CGMP compliance and product quality obligations.

537. In particular, FE6 explained that Morgantown's yearly budget, which set the number of doses Morgantown was expected to produce, put enormous pressure on the facility to meet extraordinary production goals. FE6 stated that the budget was approved by Defendant Malik and Mylan's Global Chief Operating Officer, Dr. Hari Babu. If Morgantown leadership proposed a production target that Defendant Malik felt was not ambitious enough, he would say so. FE6 reported that in 2012, Morgantown produced more than 21 billion doses. Yet, FE6 explained, as Morgantown began to produce more complex medicines, the facility's regulatory compliance and quality requirements also became more complex and time-consuming. As an example, FE6 explained that equipment now needed to be broken down, cleaned, and inspected more frequently. However, FE6 explained that Morgantown's production targets failed to account for this, and continued to budget unrealistic production volumes that, year after year, the facility failed to meet. FE6 stated that Morgantown's budget failed to account for the fact that "changing the product we were producing in the plant was going to change our capability to meet" management's production targets.

538. FE6 reported that these issues were frequently discussed at weekly Morgantown production meetings that FE6 attended throughout 2014 and 2015, along with Mylan's Vice President of Operations, the Head of the Morgantown facility, and the Heads of Quality and

Manufacturing at Morgantown, respectively, among other senior executives. FE6 stated that the “consistent drumbeat” at these meetings was that, given the resources available to Morgantown and the complexity of the products, it was impossible to meet both the facility’s production demands and its product quality responsibilities. FE6 stated that the supervisors who attended these meetings consistently reported that “there was not enough time in the day” to break down and clean equipment properly before moving on to the next product. Likewise, FE6 reported that the executives in attendance at these meetings frequently discussed the enormous backlog of unresolved investigations into failing quality testing results: it was “always about the backlog.”

539. FE6 reported that, as FE6 discussed with the facility’s Head of Quality, Morgantown’s CGMP compliance went “downhill” as a result of its efforts to meet management’s production goals, and the facility began to receive negative observations from the FDA.

540. FE6 reported that despite the strain on Morgantown’s operating capacity, Defendant Malik insisted on cuts to Morgantown’s quality budget every year. FE6 reported that these cuts were not informed by Morgantown’s quality compliance needs. Instead, Defendant Malik would simply order Morgantown personnel to cut an arbitrary amount from the budget or lay off an arbitrary number of employees.

541. Likewise, as discussed above, FE1 reported that, for years prior to the start of the Relevant Period and throughout the remainder of FE1’s tenure at the Company, Morgantown’s severe CGMP and data integrity issues, including widespread “testing into compliance,” were a direct result of the enormous volume of drugs Mylan pushed through the facility. Likewise, FE1 explained that the enormous backlog of unresolved investigations was a function of the overwhelming pace and scope of production at Morgantown. According to FE1, it was not

feasible to adequately investigate all of the quality failures observed at the facility without crippling production. Moreover, as discussed above, FE1 reported that Mylan performed product quality testing on no more than 5% of the drugs manufactured at Morgantown because production demands made broader testing impossible.

542. Similarly, FE2 reported that Morgantown’s CGMP failures, including its widespread practice of “testing into compliance,” was driven by the facility’s overwhelming production volume. FE2 reported, for instance, that Quality Assurance was understaffed throughout FE2’s tenure and because of the speed at which Mylan insisted product be produced, a single technician was often responsible for inspection and analysis of 12 or more manufacturing “rooms” during a single shift—far too many to allow for a thorough investigation of defects and anomalies, or compliance with other CGMP requirements.

543. Likewise, FE2 stated that while two or more quality assurance technicians were required to perform certain tasks in “high potency” manufacturing rooms (rooms in which fentanyl and other dangerous products were made), supervisors instructed FE2 and others to perform those tasks alone in order to keep up with the facility’s volume. In addition, if defects or anomalies were reported in these sensitive rooms, supervisors would complain that tasks were not being completed quickly enough and the issues would receive only a “band-aid” fix to keep production moving. In another example (similar to examples ultimately cited in the FDA’s 2018 Form 483, discussed below), FE2 reported discoloration of levothyroxine tablets indicating cross-contamination, but Mylan’s Quality Assurance Operations Manager instructed FE2 to push the defective tablets through. FE2 further reported that technicians were encouraged to refrain from swabbing rooms and equipment to check for foreign drug residue—a critical step in preventing crosscontamination—in order to avoid production delays.

544. Similarly, FE4, stated that Morgantown’s “astronomical” production volume “was not a cause, it was the cause” of the facility’s CGMP failures, including pervasive “testing into compliance.” Morgantown simply did not have the resources to comply with its regulatory obligations given the extraordinary volume of product Mylan’s senior management attempted to push through the facility.

545. FE4 explained that Mylan would sell product before it was manufactured. Thus, there was tremendous pressure to push volume through Morgantown in order to meet the Company’s sizeable commitments. Quality Control was perceived as the “bottleneck” stopping drugs from getting out the door. There were only about 100 people in the quality department testing materials being made and sold by over 4,000 manufacturing and salespeople. FE4 stated that employees were “always under high pressure” and “always behind” in the lab. Analysts were expected to do all their testing in one day, generate data overnight, and come in the next day and test something new. This left almost no time for something to go wrong. FE4 reported that investigations of failing or anomalous results could only take place if they could be “squeezed in.” And, as discussed above, when investigations were conducted, they were not meaningful. Failing analyses would often be passed off to someone else for re-testing, who would then come back to the original analyst, perhaps a month later, and ask them to sign off on analyses showing passing results and to state that the initial failing results were the product of analyst error. FE4 stated, “How am I supposed to [affirm that] I pipetted wrong a month ago?”

546. According to FE4, trying to do all the required testing under one roof was “insane.” No other facility in the world, including China or India, pushed out as many different products at that much volume. FE4 stated that “there was no way” Mylan’s leadership, including its senior Quality executives, could have failed to know that the volume was “insane” and

adequate investigation was impossible. Anyone with a background in this industry would have understood the resources required to adequately investigate and test the products given the volume.

547. In addition, according to FE4, there was so much volume that there was not enough equipment to go around, and certainly not enough time to clean and prepare it appropriately. The maintenance was “so bad” that the Company wanted analysts to get trained to fix their own instruments because the department in charge of it could not keep up.

548. According to the Amended Complaint in the W.D. Pa. Mylan Class Action, FE7 was a Quality Assurance Supervisor from prior to the Relevant Period until November 2018 and was responsible for supervising technicians who conducted quality assurance testing at Morgantown. FE7 likewise reported that it was “almost impossible” to comply with the FDA’s quality requirements because the facility was “going full barrel” and “producing a ton of product.” Indeed, FE7 reported that at three meetings between the end of 2015 and November 2016—even before the FDA issued the 2016 Form 483 to Morgantown—John Sylvester, Head of OSD Site Operations at Morgantown, stated that the volume and pace of production was causing, and would continue to cause, significant CGMP compliance problems, particularly around cleaning and contamination. FE7 stated that Sylvester was concerned that these CGMP issues were accelerating because customers were demanding smaller lots of products, which entailed more turnover, and therefore more cleaning and inspection.

549. Bloomberg conducted its own investigation that corroborates these Former Employee reports. After a year-long investigation into the generic drug industry, Bloomberg reported that numerous former employees at Mylan’s Nashik plant stated that “testing into compliance” was widespread at the Company, driven by pressure from the top to churn out large

volumes of drugs. According to Bloomberg, these former employees explained that “investigating why a drug fails testing is time-consuming . . . whether due to time pressure, ignorance or just laziness,” so it was often “easier to say the tester spilled some of the sample or made some other mistake and then test again.” Then, if the batch passed the second test, “it was assumed to be fine.” Likewise, Mylan employees also explained that because quality control teams “faced constant pressure to get the drugs out the door as fast as possible,” it was “harder to properly investigate why a batch failed.”

**6. Following the 2016 Morgantown Inspection, Defendant Malik Privately Met with the FDA to Fend Off Further Agency Action**

550. Following the Morgantown inspection, and unbeknownst to investors, the FDA privately wrote to Mylan demanding answers. The FDA noted that the agency’s inspections “raised questions regarding the integrity and reliability of data generated” by Mylan’s quality control and assurance functions. As later reported in *Bottle of Lies*, Mylan privately responded to the FDA in January 2017 and attempted to explain away the agency’s findings. But Mylan’s explanations were vague, contradictory, and factually unsupported. For instance, Mylan told the FDA that one of the frequently occurring error messages at the Nashik plant the agency suspected was connected to Mylan’s practice of “crashing files” was “not related to the disconnection of the Ethernet cable or power cord.” The Company admitted in non-public correspondence, however, that “[i]t is not evident through retrospective review whether these disconnection events were caused by manual intervention of cables (accidental knocking of cables)” and failed to support its claim that any “knocking” of cables was “accidental.” Similarly, Mylan vaguely ascribed another recurring error message—which was recorded 150

times in seven days—to a software setting that caused unintended consequences but was unable to provide a complete explanation to the agency.

551. The FDA rejected Mylan’s excuses. As discussed above, on April 3, 2017, the agency publicly issued a warning letter, addressed to Defendant Malik, in connection with the Nashik plant. The Nashik warning letter summarized the CGMP and data integrity violations FDA inspectors had discovered, citing the Company’s failure to “thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications.” The FDA also highlighted the fact that analysts at the Nashik plant had “invalidated . . . initial failing result[s] without adequate investigation, performed re-testing, and then reported the . . . results of these replicate re-tests.” The FDA required Mylan to develop a remediation plan under the supervision of a consultant.

552. The public, of course, remained unaware that the impetus for the Nashik inspection had been a whistleblower report detailing systemic CGMP and data integrity violations throughout Mylan, including at Company’s flagship Morgantown facility. The public also was unaware that, as the whistleblower reported, the FDA had indeed discovered that Morgantown was rife with the same profound product quality failures cited in the Nashik warning letter, including widespread “testing into compliance.”

553. Defendants knew it was critical that they dissuade the FDA from also publicly issuing Mylan a warning letter concerning its key Morgantown facility. A publicly issued Morgantown warning letter would indicate that Mylan’s CGMP and data integrity problems were not isolated to one or two plants in India, but were systemwide. As discussed above, if the FDA found that Mylan’s product quality and data integrity issues were widespread, then penalties, sanctions, and remediation requirements could escalate dramatically. In addition, a Morgantown

warning letter would further indicate to the public that these violations, were pervasive within Mylan’s flagship manufacturing facility that was responsible for producing approximately 20 billion doses per year and was critical to its core U.S. operations. Accordingly, a public warning letter aimed at the heart of Mylan’s U.S. operations would severely undermine Defendants’ repeated statements touting the Company’s “advanced” and “state-of-the-art” quality assurance and control processes as providing Mylan with a significant competitive advantage.

554. Mylan was already facing shareholder blowback over Congressional allegations of Medicare fraud and antitrust violations in connection with EpiPen, outsized executive compensation (including a \$100 million payout to Mylan director Robert Coury), and high-profile acts of dishonesty by its leadership (including Defendant Bresch’s misstatements about her academic qualifications). Indeed, on May 30, 2017—as Mylan was meeting with the FDA about Morgantown—a group of Mylan’s major institutional shareholders issued a letter urging fellow investors to oppose the reelection of Mylan’s directors at the Company’s upcoming shareholder meeting. The letter accused the Mylan Board of reaching “new lows in corporate stewardship in 2016” in connection with “extraordinary and egregious” compensation paid to the Company’s leadership that “came amid a public and regulatory backlash for the price-hiking controversy involving Mylan’s EpiPen.” A few weeks later, independent proxy advisory firm Institutional Shareholder Services (“ISS”) also issued a report recommending that shareholders vote against reelection of most of Mylan’s Board, including Defendants Malik and Bresch, because the Company’s legal and regulatory exposure arising from the EpiPen scandal and alleged price fixing of generic drugs had caused “significant destruction in shareholder value.” A public airing of Morgantown’s egregious CGMP problems was the last thing Defendants needed.

555. Accordingly, in April 2017, less than three weeks after the FDA issued the Nashik warning letter, Defendant Malik and six other senior Mylan executives met with the agency to attempt to fend off further regulatory action, including a warning letter, directed at the Morgantown facility. Katherine Eban reported in *Bottle of Lies* that at that meeting, FDA officials grilled Defendant Malik and the other senior executives about why Morgantown analysts had failed to investigate OOS and other anomalous test results and instead had retested the drugs and recorded passing results. As Eban reported, FDA representatives told Defendant Malik they were “stunned” by Mylan’s “egregious” violations, which they said led the agency to question whether the Company was being “transparent at all of its sites.”

556. The FDA’s investigation made clear that the Morgantown facility was rife with the same egregious CGMP and data integrity violations discussed in the Nashik warning letter. Nevertheless, as discussed above, following the public issuance of the Nashik warning letter, Defendants downplayed it and concealed the widespread and systemic issues plaguing Mylan’s far more significant Morgantown facility. Defendants claimed that the Nashik warning letter reflected discrete, one-off technical issues related to “evolving” FDA standards. Defendants also claimed that the problems were confined to Nashik—“one of Mylan’s 50 manufacturing sites”—and would not interrupt production or have a material impact on Mylan’s business. Meanwhile, Defendant Malik continued to lobby the FDA in order to forestall a Morgantown warning letter. Defendant Malik emphasized Morgantown’s importance to Mylan’s business, assured the agency that the facility “was founded upon the principle of integrity,” and blamed analysts’ retesting without investigation on an old SOP that needed to be updated.

557. FDA staff, in two separate divisions found Defendant Malik’s explanations not credible and recommended further regulatory action to address Morgantown’s CGMP

noncompliance. As discussed above, the international investigators who visited the Morgantown site had rated Morgantown “Official Action Indicated,” and the FDA had already drafted a warning letter sanctioning Morgantown. But that warning letter was never issued. Eban reported that in July 2017, over the strenuous objections of staff from both divisions, an FDA lawyer downgraded the investigators’ findings from “Official Action Indicated” to “Voluntary Action Indicated.” The same lawyer also decided to send an untitled letter to Mylan that was not visible to the public. Notably, this was the second time in two years this same lawyer had downgraded expert investigators’ findings adverse to Mylan and concealed the agency’s response, according to Eban. Yet, as Eban reported, even this lawyer acknowledged in an email to irate agency staff that the Company’s improper retesting practices were “more widespread and that Mylan’s investigation was insufficient.”

## **7. Defendants Create a “Façade of Documents” Hoping to Appease the FDA**

558. Defendants understood that Mylan’s widespread data integrity issues, particularly those at Morgantown, were driven by the Company’s emphasis on speed and volume. Meaningful and timely remediation of those failures would entail supply interruptions, reduction of volume, and expensive plant remediation. As discussed above, however, Defendants were already facing intensifying shareholder displeasure and could not afford to publicly halt or reduce production at Mylan’s flagship plant or announce that this key facility required an expensive makeover. Indeed, announcing a reduction in Mylan’s generic portfolio or a halt in production at a key plant would be particularly damaging to Defendants, because, as discussed above, they had repeatedly touted Mylan’s operational capacity as giving the Company a distinct competitive advantage in an era of generic drug price erosion. A public acknowledgment that Mylan’s regulatory obligations made it difficult or impossible to maintain these competitive

advantages would (and, at the end of the Relevant Period, ultimately did) push Mylan shareholders over the edge.

559. Instead, after prevailing upon the FDA to allow Mylan to voluntarily remediate Morgantown, Defendants made superficial changes designed to create the appearance of reform. As yet another whistleblower from inside the Morgantown plant later privately told the FDA in early 2018, Mylan’s management, instead of working to remedy problems, was more focused on creating a “façade of documents” to fend off the agency. Katherine Eban reported that, according to the whistleblower, Mylan brought in a team of employees from India to rapidly close out a backlog of investigations into failing test results and defective products at Morgantown. Plant employees were told not to question their work. The whistleblower told the FDA that Mylan had developed an “embedded culture” of fraud and made no real effort to correct it.

560. According to the Amended Complaint in the W.D. Pa. Mylan Class Action, Former Employees of Mylan corroborated the FDA whistleblower’s account that Mylan did not actually address the underlying issues raised by the 2016 Form 483. For instance, FE1 “agreed completely” with the 2018 whistleblower’s report that, following the 2016 Form 483, Mylan was more concerned with creating a “façade of documents” to give the appearance of regulatory compliance, than with remediating the facility’s quality failures. FE1 reported that during FDA inspections, Morgantown employees wrote, signed, and backdated SOPs to present to agency inspectors. Those “backdated” SOPs were created while the FDA was “waiting in another room,” and included the language that Mylan believed the FDA wanted to see. Similarly, FE1 recalled that the “FDA would be in one hallway and [Mylan employees were] laying tape in the next hallway to segregate clean versus dirty equipment.”

561. Following the issuance of the 2016 Form 483, FE1 attended meetings with senior Mylan personnel, including Morgantown Head of Quality Kupec and Senior Director of Quality Assurance Operations Koski, to discuss the FDA's findings. FE1 stated that the focus of the meetings was not about how to remediate the serious CGMP violation the FDA identified, but how to formulate a response defending the Company by the agency's deadlines. According to FE1, this was reflected by the fact that the meetings petered out not long after the Form 483 was issued. "We went from a couple meetings a day, to a couple a week, to none at all." In particular, FE1 reported that Mylan's practice of re-running tests until they passed was "definitely a topic of discussion" following the FDA's 2016 Form 483, but the Company made no real effort to address it. FE1 reported that the FDA's findings in the Form 483 were extremely serious: "In reality with that kind of report in this industry, the FDA would have been well within their right to deadbolt the door." Yet, FE1 reported, the Company's response was not serious.

562. Likewise, FE6 reported that Mylan failed to implement any significant remediation measures at Morgantown following the 2016 Form 483. Indeed, far from allocating additional money to Morgantown to finance meaningful remediation, FE6 reported that Defendant Malik, again, insisted on cuts to Morgantown's quality budget for 2017. FE6 explained that any remediation the site implemented would have to come out of its (now reduced) ordinary operating budget, which was already inadequate to meet the facility's quality compliance needs.

563. FE3 agreed with the 2018 whistleblower that Mylan was focused on creating a "façade of documents" to appease the FDA. FE3 reported that Mylan's remedial efforts following the 2016 Form 483 were essentially limited to addressing the manner in which observations were described in documentation, not to addressing the most egregious CGMP

failures. FE3 stated that it was apparent from meetings with Morgantown’s Quality Director that Mylan was anxious to avoid any remediation that would require the Company to halt production at the facility. FE3 stated that management was “afraid that if they got to heart of problem that would mean they had to stop testing.” Because Mylan could not afford to halt production, it addressed only those superficial items that would not interrupt Morgantown’s regular functioning.

564. FE2 echoed other Former Employees in this regard. FE2 reported that the Company did little in the way of remediation beyond changing some of its SOPs—efforts FE2 described as “superficial.” No real effort was made to remediate the enormous process and integrity failures that were widespread throughout the plant or address the overload of production volume at the core of those failures.

565. Similarly, FE8 who, according to the Amended Complaint in the W.D. Pa. Mylan Class Action, was a Technical Area Lead in Manufacturing at Mylan from 2016 to 2018, reported that Mylan made no real effort to address the issues identified in 2016 Form 483, despite the fact that employees recognized the issues raised by the FDA were serious and required substantial remediation. FE8 recounted that Defendant Malik held a town hall meeting at Morgantown in the first half of 2017. At this meeting, plant employees told Defendant Malik that Morgantown’s quality function was stretched too thin and that the plant needed to increase its headcount in order to meaningfully address its CGMP compliance issues. Defendant Malik “immediately dismissed” these concerns. FE8 reported that remediation was not “taken seriously” by Mylan management until after Mylan received another Form 483 directed at Morgantown in April 2018, as discussed below.

566. In this way, Mylan attempted to quietly spread out its remediation over a longer time-horizon and at least defer the most painful fixes until management was on better footing with investors. Defendants gambled that Mylan could appease the FDA long enough to avoid yet another painful and inopportune public disclosure of wrongdoing. All the while, Defendants continued to conceal the serious product quality problems afflicting the Morgantown plant, the scope and cost of required remediation, and the exponentiated risk of further adverse legal and regulatory consequences, including a warning letter or consent decree, if the FDA found that the Company had failed to timely address the deficiencies on its own. However, Defendants continued to receive numerous warnings following the 2016 Morgantown inspection that the facility's product quality processes were woefully deficient. Indeed, between the start of the Relevant Period and the FDA's April 2018 inspection, Mylan issued recall notices for at least 15 different drugs and dosages manufactured at the Morgantown plant, including drugs referenced in the 2016 Form 483, for reasons that included: "Failed Dissolution Specifications; three month stability time point"; "Failed Impurities/Degradation Specifications: OOS results for known compound"; "Presence of Foreign Tablets/Capsules [in bottles]"; "Chemical Contamination: out of specification results for impurities were found to be the result of contamination of product from vapors associated with paint thinner used in repair of the manufacturing room"; and "Microbial Contamination of Non-Sterile Products."<sup>49</sup>

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<sup>49</sup> Note that Mylan did not publicly report the drugs manufactured at each of its facilities and would not disclose this information even when asked by analysts. Among other things, Plaintiffs cross-referenced drugs identified in Mylan's Morgantown Form 483's with FDA recalls.

**8. During its March 2018 Morgantown Inspection, the FDA Found that Mylan’s CGMP and Data Integrity Failures Were Still Widespread**

567. In early 2018, the FDA received the whistleblower report discussed above. On March 19, 2018, the FDA, acting on that report, conducted another surprise inspection of the Morgantown plant. As in 2016, the investigative team was unusually large and sophisticated. The eight-member team included international experts, an FDA Center employee, and two chemists/biologists.

568. The FDA’s investigators conducted a four-week inspection of the Morgantown plant and on April 12, 2018 privately issued a lengthy, scathing Form 483 addressed to Kimberly Kupec, Mylan’s Head of Quality at Morgantown. The 2018 Form 483 cited the same egregious CGMP and data integrity violations about which the FDA had repeatedly warned Defendants and Mylan’s senior leadership, including in the 2016 Form 483. Just as it did in 2016, the FDA concluded that the Morgantown facility’s “[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity strength and purity.” In total, the FDA made thirteen observations identifying specific categories of CGMP and data integrity violations at Morgantown facility, with multiple examples within each category.

569. Among other things, the FDA found that, just as in 2016, Mylan’s practice of “testing into compliance” was still widespread at Morgantown, specifically finding that “[l]aboratory analyses are repeated until passing results are obtained.” The 2018 Form 483 cited multiple instances involving several different drugs in which failures for cleaning verification tests were obtained, but equipment was “re-swabbed and re-analyzed” until the desired results were obtained. Moreover, the FDA found that even where Mylan opened an investigation, they

were frequently never closed out before the suspect drugs were released to the public, including many cases in which the Company observed “in-process results that were out of specifications.”

570. Just as in 2016, Mylan continued to invalidate failing results and re-test drug products and equipment without adequate investigation. For example, investigators discovered that despite Mylan’s high swab failure rate for cleaning “indicating that corrective action has not been effective,” the Company failed to investigate the root cause of the repeated failures. Remarkably, failing swabs “were categorized as ‘inconclusive’ and invalidated if a re-swab in another location of the equipment yielded passing results.”

571. Likewise, the 2018 Form 483 cited numerous instances in which Mylan dismissed failing results without investigating the batch failures, just as in 2016. For instance, Mylan received a complaint that drug tablets had a “high percentage of specks” on the surface yet failed to investigate whether they were caused by cross-contamination (notwithstanding the Company’s chronic contamination and sanitation issues). Instead, Mylan dismissed the defect as “only on the surface” of the tablets, yet failed to inspect the interior of the tablets to determine whether this rationale was correct. In another example, Mylan received a complaint about dark blue spots on tablets, which contained trace metals associated with stainless steel. Mylan concluded that “likely point of introduction cannot be determined,” yet never evaluated the equipment used in production as a potential contaminant.

572. Accordingly, FDA investigators once again concluded that Mylan “fail[ed] to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed.”

573. In addition, and as in 2016, investigators found that Mylan made changes to batches without investigating the impact of the change or properly documenting it. Investigators noted that one such changed batch was later subject to an investigation for “dissolution failure” and another for “excessive broken tablets.”

574. And, again as in 2016, the FDA pointed out additional instances in which Mylan invalidated failing test results for apparently pretextual reasons. In one example, Mylan’s Quality Unit attributed failing test results to the operators’ lack of training, but this “was not supported by evidence because all involved operators were experienced.” The Quality Unit failed to rule out defects in the drug but still released the batch. Likewise, the Quality Unit attributed failing test results to the fact that the analysis was conducted “outside . . . stability time range,” but the data clearly showed the analysis was conducted well within the time range.

575. The FDA also found that the Morgantown facility was again failing to meet basic cleanliness requirements. Investigators reported that Mylan experienced dozens of visual cleaning failures, “for which a swab or an investigation were not performed” at all. Even where drug test failures were identified because of inadequate cleaning, Morgantown’s managerial Quality Unit did not require equipment to be cleaned or product manufactured on the contaminated machine to be inspected.

576. As discussed below, the FDA ultimately issued a warning letter to Mylan arising out of the 2018 Morgantown inspection. The FDA was clear that Mylan had already warned that its re-testing practices were improper, writing that “the unjustified invalidation of failing test results is a repeat violation.”

577. Importantly, the FDA investigators found that Mylan’s management was responsible for Morgantown’s egregious CGMP and data integrity failures. In the 2018 Form

483, investigators wrote that they “observed numerous instances of a lack of appropriate oversight by the Quality Unit and a failure to follow” Mylan’s own operating procedures, which the Company had submitted to the FDA. Significantly, the FDA excoriated “senior management” for failing to “ensure continuing suitability and effectiveness of quality systems through governance,” including through a variety of management-level oversight organs, such as the “Trending Review Board, Annual Product Review,” and “Quality Site Council,” as, again, was required by Mylan’s own operating procedures submitted to the agency. Among other things, management failed to review and approve changes in controls, equipment, and facilities.

578. Likewise, changes to written procedures were not reviewed and approved by management, as the Company’s operating procedures required. Indeed, when pressed by investigators, the Quality Unit could not “provide a listing of all manufacturing changes made within the LIMS system [Mylan’s “Laboratory Investigation Management System”] without a change control since November 2016 as these changes are not tracked reviewed or approved.”

579. Moreover, the FDA found that “[d]rug product production and control records [were] not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.” Among other things, Mylan’s Quality Unit “failed to review and close out all LIMS investigations” during the manufacturing process. Indeed, nearly 17% of the investigations opened in Mylan’s tracking system were never closed out by the Quality Unit before the drugs were released to the public—many of those open investigations “were for in-process results that were out of specifications.”

580. Finally, the FDA investigators cited additional data integrity violations, including a failure to develop “written procedures for production and process controls.” The proliferation

of additional violations corroborated the whistleblower's report that Mylan's data integrity problems had gotten worse, not better.

581. Significantly, in private correspondence with the FDA following the 2018 Morgantown inspection, Mylan acknowledged that the facility's profound CGMP failures were driven by the enormous volume the Company pushed through the facility. In the letter, Mylan's Head of Global Quality wrote, "We believe that the large volume of doses and products within the Morgantown portfolio, while it has enabled us to supply the US market with products manufactured in the US, has inhibited [Mylan's] ability to achieve the high level of control over our manufacturing processes that we expect." As numerous Former Employees, including FEs 1, 2, 4, 6, and 7 reported, this was well-known inside Mylan even before the start of the Relevant Period.

**9. Following the FDA's 2018 Inspection, Mylan Was Forced to Halt Production at Morgantown, Dramatically Reduce its Portfolio, and Implement Expensive Remedial Measures**

582. In April 2018, after the FDA issued the 2018 Form 483, Defendants were finally forced to do what they should have done before the start of the Relevant Period. First, Mylan was forced to halt production at Morgantown while the Company's CGMP and data integrity processes were being remediated in order to protect consumers from adulterated products. According to the Amended Complaint in the W.D. Pa. Mylan Class Action, FEs 2, 3, 6, and 8 confirmed that production at the Morgantown facility came to a stop following the 2018 Form 483. Second, Mylan was forced to dramatically reduce—by close to two-thirds—the overwhelming production volume that made it impossible to adequately perform mandatory quality control functions, including thoroughly testing all drugs and investigating failing results.

Third, Mylan was forced to implement comprehensive remedial measures under consultant supervision and ensure those measures were validated and scalable before resuming production.

583. Mylan did not disclose any of these facts to the public. Instead, on April 20, 2018, Mylan announced that it was laying off 15% of the employees at Morgantown. In a statement issued to news outlets announcing the layoffs, Mylan stated, “[W]e’ve realized that our Morgantown plant needed to be rightsized to be less complex. The right-sizing is consistent with discussions we are having with 180. In the weeks following the issuance of the 2018 Form 483, Mylan was also forced to recall numerous drugs manufactured at Morgantown. For instance, in the three weeks following the FDA’s inspection, Mylan recalled at least seven different drugs and doses manufactured at Morgantown, including drugs that were flagged in the 2016 Form 483. The reason stated for each of the recalls was “CGMP violations.” Still, Defendants failed to disclose the Form 483, its findings, the halt in production, or Mylan’s dramatic reduction in its generics portfolio. Through the remainder of the Relevant Period, Mylan continued to withdraw additional drugs and doses manufactured at Morgantown because of CGMP failures, defects, and contamination.

## **I. The Truth Emerges**

### **1. June 27, 2018: Disclosure of the Morgantown Investigation and 2018 Form 483**

584. On June 27, 2018, shortly before the market closed, Bloomberg issued a brief news alert reporting that, as described at ¶¶ 567-581 above, in the spring of 2018, the FDA had conducted a lengthy inspection into the Morgantown facility from March 19, 2018 to April 12, 2018. Specifically, Bloomberg reported that the FDA “made 13 observations” after inspecting Mylan’s Morgantown plant, and that, among these observations, the FDA noted, “equipment and utensils not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination

that would alter the safety of the drug product.” The 2018 Form 483 findings to which Bloomberg directed readers are described above in full.

585. Analysts understood that the FDA’s conclusions were unusually serious. Cantor Fitzgerald’s analyst wrote on June 29, 2018, “Our consultants agreed that the inspection was serious and not routine (maybe whistleblower). This is because there were 9 people at the inspection, and it took a long time to complete. The letter [2018 Form 483] was 32 pages, which is quite lengthy. Also, the makeup of the inspectors was unusual. Inspectors are usually local, but this inspection included a national expert, FDA Center employee, and two chemists/biologists.” Cantor also warned that the situation may be more dire than Mylan let on because a Form 483 “could turn into a Warning Letter or even a Consent Decree if the company does not address it in a timely and comprehensive fashion. This is because most of the observations could be summarized as quality control issues (not enough time or people addressing problems).”

586. On this news, Mylan’s share price fell \$1.12 per share, or approximately 3%, from \$37.45 per share to \$36.33 per share.

587. Defendants continued to conceal the full relevant truth and prevented the further decline of Mylan’s stock price by continuing to make false statements and omit material facts about Mylan’s purported commitment to quality. In response to Bloomberg’s disclosure of the Morgantown investigation and the FDA’s issuance of the Form 483, Mylan issued a press release minimizing the impact of this development and reassuring investors that “Mylan is committed to maintaining the highest quality manufacturing standards at its facilities around the world,” and “confident in the quality, safety and efficacy of our drug products.”

588. The Company downplayed the Morgantown inspection as one of its regular inspections “by health authorities to ensure compliance,” and noted that “the company has submitted a comprehensive response to the Agency and committed to a robust improvement plan.” Mylan reassured investors that it would “continue to maintain a close dialogue with the Agency and is fully committed to working with FDA to address its observations.” Again, Defendants failed to disclose that the FDA’s inspection had forced Mylan to halt production at Morgantown, significantly reduce the Company’s generics portfolio, and had materially increased operating costs.

**2. August 8, 2018: Disclosure of the “Restructuring and Remediation Program in Morgantown”**

589. On August 8, 2018, during Mylan’s first earnings call since the public learned of the FDA’s investigation at Morgantown earlier that spring, Defendant Malik disclosed that, at least in part due to its “robust . . . improvement plan” following the issuance of the FDA’s 2018 Form 483, Mylan had “undertaken a restructuring and remediation program in Morgantown.” This program included the “discontinuation of a number of products” and was “aimed at reducing complexity at the facility.” Malik added that these measures “have temporarily had a negative impact on production levels, product supply and operations.” Specifically, Defendants disclosed approximately \$87 million in expenses related to the Morgantown restructuring and remediation program; a decline in total revenue of \$2.8 billion or 5%; and a 22% decline in North America revenue driven, in part, by “the impact of the restructuring and remediation program in our Morgantown manufacturing facility.”

590. Nevertheless, Mylan’s executives attempted again to minimize the disclosure and concealed material facts, assuring investors that the Morgantown restructuring “impact is temporary,” that Mylan’s “profitability levels are sustainable,” that the “remediation and

restructuring is going to be completely effective,” and that “long term these actions will only further strengthen our Morgantown site.” Defendant Malik specifically assured investors that the restructuring “was not triggered just by this FDA inspection. It was part of . . . this year’s plan actually to right size it. Because we have observed that it will be very difficult for us to manage this sort of complexity which Morgantown has, which [sic] 20 billion doses, with evolving FDA expectations.” Defendant Bresch added, “[W]e will be seeing that continued turnaround and us continuing to be able to re-bring volume back up to where we said we were bringing it back up to which is obviously streamlined from where the facility has been historically. So kind of that rightsizing and remediation is all happening simultaneously.”

591. On this news, Mylan’s share price fell \$2.62 per share, or approximately 7%, falling from \$39.23 per share to \$36.61 per share.

592. Analysts reacted accordingly, taking the news of the Morgantown remediation and restructuring into account in their models but relying on Defendants’ reassuring statements and remaining encouraged about the Company’s outlook. Barclays’ analyst stated, “Clearly MYL’s initial print is a disappointment,” noting that while “regulatory execution has been the limiting factor,” “we believe MYL’s US generic business has one of the deepest pipelines in the industry.” Deutsche Bank updated its model for Mylan based, in part, on “gross margin pressure from remediation at [the] Morgantown facility,” but noted, “While we lowered our estimates and target, we are reiterating our Buy rating. With the significant re-basing of the outlook, we are hopeful that MYL is shifting to a ‘meet or beat’ mode, which should be well received by investors if the company delivers.” Deutsche Bank elaborated, “While the Morgantown remediation will have a temporary adverse impact on sale and margins, management expects longer-term benefits as it reduces complexity at the facility.”

593. J.P. Morgan lowered its price target from \$53 to \$48 due, in part, to “remediation costs at the company’s Morgantown facility (which appear more extensive than we had appreciated),” and to the fact that the restructuring “is having a larger-than-expected impact on results.” Nevertheless, the J.P. Morgan analysts were still optimistic that “Mylan has commenced a strategic review as it looks to unlock value from its platform . . . [W]e believe there are a number of paths for the company to unlock value from here.” J.P. Morgan explained that although “Morgantown represents a larger headwind than we had anticipated for 2018 . . . the issues at Morgantown appear manageable.” BTIG’s analyst also took comfort in Mylan’s soothing statements, noting, “While Mylan does have more work to do at its Morgantown manufacturing facility[,] we think its remediation plan and restructuring will eventually lead to greater efficiency which should benefit the [company] down the road.”

594. Several analysts were more skeptical. Morgan Stanley’s analyst stated, “Morgantown facility issues disappointing. MYL disclosed significant operational issues which are negatively impacting business execution.” And Wells Fargo expressed frustration with the Company, reporting, “Mylan’s reported North American revenues (-22% YoY) were impacted negatively by the company’s restructuring and remediation program at its Morgantown plant. We think it is important that Mylan explain further details on what caused the negative impact and how this was not anticipated. We believe whenever there is a significant headcount reduction in a manufacturing environment, there is always a potential for issues to emerge. As investors may recall, we published our takeaways on the layoffs at the Morgantown plant in April, but were only made aware of them through local press reports, not through direct communication from Mylan.”

595. FiercePharma's August 9, 2018 reporting noted that worse times might be ahead for Mylan: "But besides the plant downsizing, the company is still having to address lots of shortcomings that the FDA laid out in two Form 483's in two years. The facility had been nicked in 2016 with a 23-page citation with five observations, some of them similar to those listed in the April report."

596. On November 5, 2018, however, Mylan held its earnings call for the third quarter of 2018 and further minimized the news of the Morgantown restructuring and its dramatic impact on Mylan's bottom line. Defendants attempted to regain investors' confidence by "celebrating the broad contribution" that the Morgantown restructuring has had on the business, claiming that this development "may have been misunderstood by the investment community." Defendant Malik reminded investors that "we did not expect to have any significant new product launches from the site in 2019," and although the remediation program caused a "temporary disruption in supply of certain products for our customers and reduced volume in North America generic sales . . . the value related to the rationalized product is not proportionate to the reduced volumes of those commoditized products."

597. In response to an analyst's question on "the impact the remediation is having on both your top and bottom line adjusted results as well as any more granularity on when in '19 we can expect the operations to begin to normalize at that facility," Defendant Malik dodged, reminding analysts that Mylan had purportedly "undertaken the remediation and restructuring . . . to keep this with the FDA's evolving standards" and to "rationalize and simplify the plant and reduce the complexity." By this point, however, the Company had disclosed that costs associated with the restructuring had reached \$98 million.

**3. November 9, 2018: the FDA Warning Letter Concerning CGMP Violations at Morgantown**

598. On November 9, 2018, the FDA issued a warning letter to Mylan in connection with the Morgantown facility, addressing the letter to Defendant Bresch. The letter, which was consistent with what the 2018 Form 483 previously disclosed, stated that it “summarize[d] significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals” that had been laid out in the Form 483 delivered to Mylan on April 12, 2018. The warning letter concluded, “Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of” federal law.

599. The Morgantown warning letter summarized the CGMP and data integrity violations FDA inspectors had discovered, citing the Company’s failure to “thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications.” Specifically, the warning letter stated that Mylan’s “investigations into out-of specification (OOS) results and process deviations were inadequate. Root causes did not consistently include scientifically supported conclusions.” Instead, the warning letter reiterated that failing drugs and equipment were simply retested until passing results obtained, as both the 2016 and 2018 Forms 483 had made clear to Defendants.

600. For instance, the warning letter stated that failing results were repeatedly attributed to “untrained or inexperienced operators,” but the Company failed to investigate obvious deficiencies in the Company’s manufacturing process, as numerous Former Employees reported. The FDA pointed out that as a result of this improper practice, Mylan was forced to recall “all batches of prednisolone sodium phosphate ODT within expiry from the U.S. market”

on April 30, 2018. Mylan failed to disclose these facts to investors even as it continued to tout the Company’s manufacturing processes and quality control.

601. In another example, Mylan had “opened multiple manufacturing investigation reports and trending assessments from July 2016 to October 2017 related to out-of-trend and OOS content uniformity results for metolazone 2.5 mg tablets.” Despite the fact that no root cause for these failing results had been identified, no remedial plan had been implemented, and the Company continued to observe “substantial non-uniformity . . . in multiple batches” of the drug, Mylan “continued to manufacture and release this drug product up to the time of the inspection” in April 2018. Once again, this stunning disregard for product quality and safety occurred during the period following the 2016 Morgantown inspection, in which Malik assured the FDA that Mylan would address the facility’s CGMP deficiencies.

602. The FDA’s findings left no doubt that Mylan’s senior management was responsible for the profound and widespread CGMP failures at Morgantown. Contrary to Defendants’ repeated statements touting the Company’s robust quality assurance processes, the warning letter explained, “Your firm lacks an adequate ongoing program for monitoring process control to ensure stable manufacturing operations and consistent drug quality.”

603. The warning letter targeted Mylan management’s failure to adequately institute controls at the Company to address deficiencies in Mylan’s production protocols, noting, “When significant variability is observed in one or more stages of pharmaceutical production, it is essential for executive management to support and implement effective actions that proactively address the source(s) of the variation and provide for a continued state of control.”

604. The FDA made clear that it was management’s CGMP compliance failures that were driving widespread product quality failures at Morgantown: “Your lack of rigorous

oversight of manufacturing changes continues to be a major factor in the unexpected variation observed in your drug products.”

605. Significantly, the FDA made clear that the CGMP and data integrity issues identified in the warning letter and in the 2018 Form 483—including “invalidating numerous initial OOS assay results without sufficient investigations to determine the root cause of the initial failure”—were “repeat violations at multiple sites” about which the FDA had warned Mylan on several occasions. Specifically, the warning letter stated that the FDA previously “cited similar CGMP violations at this and other facilities in your company’s network.” As examples, the FDA cited a 2015 warning letter issued in connection with three Mylan facilities in India as well as the 2017 Nashik warning letter, both of which warned Mylan about its “fail[ure] to thoroughly investigate unexplained discrepancies” and “invalidat[e]” numerous “initial out-of-specification (OOS) assay results without sufficient investigation to determine the root cause of the initial failure.”

606. The FDA concluded in the warning letter, “These repeated failures at multiple sites demonstrate that Mylan’s management oversight and control over the manufacture of drugs is inadequate . . . . Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.”

607. On November 20, 2018, the FDA posted the warning letter on its website and FDA Commissioner, Dr. Scott Gottlieb, took the unusual step of reporting the Warning Letter on Twitter. Posting a direct link to the Warning Letter, Commissioner Gottlieb tweeted: “An important aspect of ensuring drug safety is adherence to current good manufacturing practices. Recently #FDA issued a warning letter to Mylan Pharmaceuticals for CGMP violations. We expect the firm to work to resolve the issues identified by the #FDA.”

608. In a November 20, 2018 press release responding to FDA letter, Mylan admitted that it had discontinued production of some products at the Morgantown site and transferred production of some to other sites. “These actions have led to a temporary disruption in supply of certain Mylan products for customers,” Mylan said. “We understand that this current and temporary situation puts a burden on our customers and appreciate their ongoing confidence in Mylan. We will continue to work closely with our customers to mitigate any possible supply disruptions and meet the needs of the patients we serve.” In a January 18, 2019 analyst note, Leerink responded to the news of the FDA’s warning letter to Mylan regarding the Morgantown plant. Leerink’s analysts consulted a CGMP specialist, who was “not surprised that Mylan received a warning letter,” given the “severity” of the CGMP failures cited by the FDA. Leerink’s specialist noted that the FDA’s observations “raise concerns around patient safety and product quality and thus will require extensive actions to correct.”

**4. February 26, 2019: Disclosure of an 18% Decrease in Net Sales Due to the Morgantown Restructuring**

609. On February 26, 2019, Mylan released its financial results for the fourth quarter and full year of 2018. The Company reported total quarterly revenues of \$3.08 billion and yearly revenues of \$11.43 billion, a decline of 5% and 4%, respectively, compared to the prior periods. The Company also disclosed North American segment net sales of \$1.10 billion, down 16% for the quarter and 18% for the year, “primarily due to lower volumes on existing products, which was primarily driven by actions associated with the restructuring and remediation activities at the Morgantown plant.”

610. Contrary to Defendants repeated reassurances during the Relevant Period, Defendant Bresch disclosed that, to remediate Mylan’s CGMP deficiencies, the Company had “rationalized the significant portion of our commodity generics business,” including three of the

Company's highest margin products. Likewise, Defendant Malik disclosed on Mylan's earnings call that, "As part of our Morgantown remediation and restructuring activities and accelerated commoditization of oral solids, we discontinued almost 250 SKUs of highly commoditized oral solid products."

611. Defendant Malik elaborated further on Morgantown on the earnings call:

After the April 2018 inspection and receipt of a 483 form, the company took a comprehensive restructuring and remediation of the Morgantown plant to address the issues that had been identified. Notwithstanding these efforts, the company received a warning letter related to the previously disclosed observations in the fourth quarter. The issues raised in the warning letter are being comprehensively addressed. The Morgantown plant continues to supply products for the U.S. market while we execute on and assess the restructuring and remediation activities.

612. Defendant Malik stated further:

No significant new product revenue is forecasted from the Morgantown plant in 2019. Also, we look at our business in North America. Only 5 of our top 50 gross margin-generating products are currently manufactured in Morgantown. We remain committed to maintaining the highest-quality manufacturing centers at our facilities around the world and to continuous improvement in a time of evolving industry dynamics and regulatory expectations.

613. Defendant Parks also disclosed that remediation costs had reached \$258 million.

In response to this news, Mylan's share price fell \$4.61 per share, or approximately 15%, from \$30.62 per share to \$26.01 per share. During the earnings call, Defendant Malik attempted to reassure analysts that the impact of the remediation was already beginning to recede and that the effects of the remediation were minimal. BMO's analyst asked, "So regarding the remediation at Morgantown, how far will that stretch into 2019? I want to understand better what [is] still involved and how long it will persist." Defendant Malik responded:

[W]e continue to execute and assess our restructuring and remediation activities at the site through this 2019. And of course, we are focused on meeting our commitments to FDA as well as customers. Now as far as any negative financial impact on the business, I think we don't see that anymore as we go into 2019. As

I've mentioned, it's, I think, largely behind us. We continue to supply from Morgantown our key products. . . . [T]here's no new big launches or no new launches. But still in 2019, from Morgantown and also from the materiality point of view, only 5 out of our top 50 North American products today come from Morgantown.

614. Defendant Bresch also attempted to attribute the Company's disappointing results to ongoing price erosion in the generics industry, noting that Mylan's ability to undertake new product launches (rather than, as she had claimed in 2017, having a large portfolio) would help Mylan combat erosion: "And I think that as we look forward, we're kind of still seeing that midsingle-digit erosion. I think the biggest difference for us is having the product—new launches be able to offset that erosion, and that's really been historically what has meant success in this business."

615. The market was disappointed by these disclosures. J.P. Morgan's February 27, 2019 analyst report stated that Mylan's news was even worse than the firm expected: "While there were low expectations heading into today's results, Mylan's 2019 earnings guide was well below our/Street expectations (~\$5.00 consensus. \$3.80-4.80 guide), and we are lowering our estimates and price target for the stock." Bloomberg's February 27, 2019 report was similarly pessimistic, noting, "Mylan NV fell by the most in three years on Wednesday, despite vows from executives to do 'everything and anything' to reverse the generic-drug maker's flagging fortunes as it nears the end of a strategic review." Bloomberg continued, "[Mylan] has also had manufacturing problems at a major manufacturing plant in Morgantown, West Virginia, which contributed to a 16 percent drop in North American sales."

616. Nevertheless, analysts continued to credit Defendants' soothing statements. BMO noted on February 27, 2019, "Morgantown remediation ongoing but disruption is largely behind them and facility continues to supply key products (no new major launches from there in 2019)."

And Leerink reported the same day, “Morgantown remediation efforts continue to progress, management believes the negative impact is in the rear-view mirror. Management indicated it continues to address the issues related to the Warning Letter. The plant continues to supply products, but no significant new product revenue from here is forecasted in 2019 and only 5 of the top 50 gross margin products come from the facility. Management doesn’t anticipate additional negative financial impact progressing later through this year.”

##### **5. May 7, 2019: Disclosure of a Q1 2019 Loss Due to the Morgantown Restructuring**

617. Finally, on May 7, 2019, Mylan reported a surprise loss for the first quarter of 2019 due, in significant part, to additional costs associated with the Morgantown restructuring. Mylan reported that its revenues and earnings-per-share were down year-over-year by 7% and 15%, respectively, driven by Mylan’s discontinuation of numerous products manufactured at Morgantown. Mylan also reported that its quarterly adjusted free cash flow had materially declined, which, on Mylan’s earnings call, Defendant Bresch attributed to, among other factors, “the Morgantown remediation.” In response to an analyst question about “the magnitude of the Morgantown remediation” and specifically its “impact on volumes,” Mylan’s Chief Operating Officer acknowledged, “we had done a number of discontinuations throughout 2018, over 100 SKUs that we had discontinued as part of a process to continue to prune our portfolio. And that certainly has played a big role in how much we’ve seen year-over-year volume declination.” Defendant Parks elaborated that the declines in Mylan’s North American business were “primarily driven by lower volumes due to changes in the competitive environment and the impact of the Morgantown plant remediation activities, and to a lesser extent negative pricing impacts.”

618. Defendants also disclosed an additional \$69.9 million in expenses stemming from the Morgantown restructuring.

619. On this news, Mylan's share price fell \$6.73 per share, or approximately 24%, from \$28.26 per share to \$21.53 per share.

620. Analysts were shocked at the extent of the impact Mylan's remediation program at Morgantown was having on the Company's business. Cantor Fitzgerald's May 7, 2019 report noted, "Takeaways from the quarter: 1) North America segment net sales of \$922.9MM, down 6% on an actual and constant currency basis, primarily driven by changes in the competitive environment and the impact of the Morgantown plant remediation activities." RBC's note the same day described that any gains in market share for certain drugs "were offset by lower overall volumes (including the impact of the Morgantown remediation activities) and lower pricing." Leerink explained, "Additional takeaways: (1) Weakness in North America (-6% Y/Y) was driven by lower volumes on existing products, primarily driven by changes in the competitive environment and the impact of the Morgantown plant remediation activities, partially offset by new product sales," and hoped for "additional color from management" on . . . the progress of the remediation efforts for the Morgantown facility." UBS's May 7, 2019 note reported, "[M]anagement stated that volumes were down due to competitive pressures and remediation activity of the Morgantown plant. We'll look for more color on the call regarding the status of the remediation and its expected impact." Zacks' May 22, 2019 report described, "Mylan's firstquarter earnings beat estimates, but sales missed the same due to currency headwinds. North America continues to witness challenges due to changes in the competitive environment and the impact of the Morgantown plant remediation activities."

621. As the relevant truth emerged about Mylan's CGMP and data integrity violations—and the attendant effects of these failures on the Company's bottom line—Mylan's share price plummeted by over 50%.

## **DEFENDANTS' FALSE AND MISLEADING STATEMENTS**

### **I. Defendants' False and Misleading Statements in 2016**

622. In its February 16, 2016 Annual Report on Form 10-K, Mylan stated, in relevant part:

#### Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits. Competitive factors in the major markets in which we participate can be summarized as follows:

#### North America

The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals. The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products. With regard to our Specialty segment business, significant sales and marketing effort is required to be directed to each targeted customer segment in order to compete effectively.

Our competitors include other generic manufacturers, as well as branded companies that license their products to generic manufacturers prior to patent expiration or as relevant patents expire. Further regulatory approval is not required for a branded manufacturer to sell its pharmaceutical products directly or through a third-party to the generic market, nor do such manufacturers face any other significant barriers to entry into such market. Related to our Specialty

segment business, our competitors include branded manufacturers who offer products for the treatment of COPD and severe allergies, as well as brand companies that license their products to generic manufacturers prior to patent expiration.

623. These statements in ¶ 622 were misleading because they failed to disclose that:

(1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by anticompetitive means to eliminate competitors of EpiPen, including, *inter alia*, by offering massive rebates to commercial insurance companies and PBMs contingent upon excluding Sanofi's Auvi-Q from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (4) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive; and (5) while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

624. In its February 16, 2016 Form 10-K, Mylan stated, in relevant part:

Specialty Segment:

Our specialty pharmaceutical business is conducted through Mylan Specialty, which competes primarily in the respiratory and severe allergy markets. For the year ended December 31, 2015, Specialty third party net sales were \$1.20 billion. Mylan Specialty's portfolio consists primarily of branded specialty injectable and nebulized products. A significant portion of Mylan Specialty's revenues are derived through the sale of the EpiPen® Auto-Injector.

The EpiPen® AutoInjector is the number one dispensed epinephrine auto-injector and as a global franchise reached \$1 billion in annual net sales for the second year in a row. The EpiPen® Auto-Injector, which is used in the treatment of severe allergic reactions, is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s. Mylan Specialty has worldwide rights to the epinephrine auto-injector, which is supplied to Mylan Specialty by a wholly owned subsidiary of Pfizer Inc. Anaphylaxis is a severe allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through a significant drop in blood pressure. In December 2010, the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health, introduced the “Guidelines for the Diagnosis and Management of Food Allergy in the United States.” These guidelines state that epinephrine is the first line treatment for anaphylaxis. The EpiPen® Auto-Injector is the number one dispensed epinephrine auto-injector. The strength of the EpiPen® Auto-Injector brand name, quality and ease of use of the product and the promotional strength of the Mylan Specialty U.S. sales force have enabled us to maintain our leadership position within this therapeutic category.

[. . .]

Medicaid, a U.S. federal healthcare program, requires pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. *Sales of Medicaid-reimbursed non-innovator products require manufacturers to rebate 13% of the average manufacturer's price and, effective 2017, adjusted by the Consumer Price Index-Urban (the “CPI-U”) based on certain data. Sales of the Medicaid-reimbursed innovator or single-source products require manufacturers to the rebate the greater of approximately 23% of the average manufacturer's price or the difference between the average manufacturer's price and the best price adjusted by the CPI-U based on certain data.* We believe that federal or state governments will continue to enact measures aimed at reducing the cost of drugs to the public.

(Emphasis added.)

625. These statements in ¶ 624 were misleading because they failed to disclose that Mylan marketed the EpiPen under an NDA but rebated Medicaid only 13% of the average manufacturer's price for sales of Medicaid-reimbursed products.

626. In the February 16, 2016 Form 10-K, Mylan stated:

OUR REPORTING AND PAYMENT OBLIGATIONS RELATED TO OUR PARTICIPATION IN U.S. FEDERAL HEALTHCARE PROGRAMS, INCLUDING MEDICARE AND MEDICAID, ARE COMPLEX AND OFTEN

INVOLVE SUBJECTIVE DECISIONS THAT COULD CHANGE AS A RESULT OF NEW BUSINESS CIRCUMSTANCES, NEW REGULATIONS OR AGENCY GUIDANCE, OR ADVICE OF LEGAL COUNSEL. ANY FAILURE TO COMPLY WITH THOSE OBLIGATIONS COULD SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS.

[. . .]

Federal laws regarding reporting and payment obligations with respect to a pharmaceutical company's participation in federal healthcare programs, including Medicare and Medicaid, are complex. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable government agencies. . .”

[. . .]

Should there be ambiguity with regard to how to properly calculate and report payments—and even in the absence of any such ambiguity—a government authority may take a position contrary to a position we have taken . . .

627. These statements in ¶ 626 were misleading because they failed to disclose that:

- (1) Mylan had in fact already failed to comply with its “reporting and payment obligations under the . . . Medicaid Rebate Program”; (2) the classification of the EpiPen was not complex and did not involve subjective decisions, but rather turned simply on whether the drug at issue had been approved under an NDA; (3) Mylan’s classification of the EpiPen was not subject to a “risk of error,” as that risk of error had already materialized; (4) Mylan’s classification of the EpiPen was not subject to “differing interpretations,” as checking on the FDA website whether a drug had been approved under an NDA or had listed therapeutic equivalents is not an interpretive exercise; (5) a government authority already had taken a position “with regard to how to properly calculate . . . payments that was contrary to a position Mylan had taken”; as the HHS IG and CMS already had determined that the EpiPen was misclassified and had informed Mylan of this determination; and (6) the disclosed risk that Mylan “could [be] subject[ed] to investigation” relating to its

“reporting and payment obligations related to . . . Medicaid” was no longer merely an unrealized risk—the risk had already materialized because Mylan was already under investigation by the DOJ.

628. In the same Annual Report filed with the SEC on Form 10-K on February 16, 2016, Defendants stated:

Our global manufacturing platform is an important component of our business model . . . with significant sites in Morgantown, West Virginia . . . We believe that all of our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for the current operations.

629. Additionally, in Mylan’s SEC-mandated “Risk Disclosures” in the Form 10-K that the Company filed on February 16, 2016, Defendants gave a misleadingly incomplete picture of Mylan’s CGMP compliance and product quality risk: Defendants stated only that “there is no guarantee” Mylan’s compliance programs and policies “will meet regulatory agency standards in the future or will prevent instances of non-compliance with applicable laws and regulations.” Moreover, Defendants stated only that Mylan “may receive” notices of CGMP violations from regulators.

630. These statements in ¶¶ 628-629 were materially false and misleading when made. It was misleading for Defendants to state that Mylan’s “facilities,” including its “significant” Morgantown site, “are in good operating condition, the machinery and equipment are well-maintained,” and that “the facilities are suitable for their intended purposes,” when, in truth, Mylan’s facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations. Far from being “well-maintained” and “suitable for their intended purposes,” both the FDA and Mylan’s own Former Employees reported that Mylan manipulated testing of manufacturing and packaging equipment by “testing into compliance,” falsifying reports, and

failing to perform required analyses in the first instance. Moreover, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Further, it was misleading for Defendants to state that Mylan’s facilities “have capacities adequate for the current operations,” when, as Former Employees reported and Mylan privately admitted, the Company’s widespread CGMP failures were a function of the enormous volume of drugs Mylan pushed through its facilities.

631. On May 3, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company’s financial and operating results for the quarter ended March 31, 2016 (the “May 3, 2016 8-K”). For the quarter, Mylan reported net income of \$13.90 million, or \$0.03 per diluted share, on revenue of \$2.19 billion, compared to net income of \$56.60 million, or \$0.13 per diluted share, on revenue of \$1.87 billion for the same period in the prior year. In the May 3, 2016 8-K, Mylan stated, in relevant part:

Specialty Segment Revenues:

Specialty segment reported third party net sales were \$247.9 million for the quarter, an increase of 17% when compared to the prior year period. This increase was primarily the result of higher volumes of the EpiPen® Auto-Injector and higher sales of the Perforomist® Inhalation Solution.

[. . .]

Adjusted gross profit was \$1.18 billion and adjusted gross margins were 54% for the quarter as compared to adjusted gross profit of \$990.6 million and adjusted gross margins of 53% in the comparable prior year period. The current quarter increase was primarily due to the incremental contribution from established products in the first quarter of 2016 as well as new product introductions, partially offset by decreased margins on existing products in North America. U.S. GAAP gross profit was \$907.0 million and \$830.1 million for the first quarter of 2016 and 2015, respectively.

632. These statements in ¶ 631 were misleading because they failed to disclose that Mylan’s net income, revenue, and gross margins were achieved in significant part because

Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

633. On May 3, 2016, Mylan held a conference call with investors on which Defendant Malik made the following statements:

[O]ur business continues to perform strongly across all areas, reflecting the powerful global manufacturing, R&D, and commercial infrastructure we have in place. And the opportunities we are seeing to leverage our expansive product portfolio across our geographies and channels as one Mylan.

In our North America generics business sales totaled \$920 million, a year-over-year increase of 8%. Growth came primarily from sales of new products and to a lesser extent from incremental sales of established products, while the pricing environment was consistent with our expectations and guidance to you.

(Emphasis Added.)

634. These statements in ¶ 633 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

635. On May 10, 2016, Defendant Bresch attended the Bank of America Merrill Lynch Healthcare Conference on behalf of Mylan. At that conference, an analyst asked Defendant

Bresch what was allowing Mylan to weather generic price erosion better than “some of the other players.”

Defendant Bresch stated:

Here in the United States, we have 400 products across every therapeutic category and have critical mass around many, many different dosage forms. It allows you to absorb that volatility. And then, not only do we have that many products, but, as I said, we manufacture 80% of what we sell. So, our ability to be nimble, to react to market opportunities, to react to customer disruption, when other players; that ability truly is not only allows you to manage through volatility, but it certainly then puts a different perspective of how you're leveraged with the customers. As our customers continue to consolidate, they need more product. Their reliance and needing for certainty has gone to an all-time high.

\* \* \*

If you look, then, not only investing, but everything from complex products to the commodity products that you've got that full offering. On top of that, having the manufacturing operating platform that is allowing you to make what you're selling, vertically integrate, and have that global supply chain.

636. These statements in ¶ 635 were materially false and misleading when made. It was misleading for Defendant Bresch to tout Mylan's vast operational capacity, as a distinct competitive advantage in both retaining customers and taking advantage of market shortages while failing to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. In fact, as investors learned at the end of the Relevant Period, Mylan's operating capacity was severely constrained, and the Company could not produce the same volume of product at the level of quality that the FDA requires and consumers demand.

637. On June 7, 2016, Defendant Bresch attended the Goldman Sachs Global Healthcare Conference on behalf on Mylan. At that conference, an analyst asked Defendant Bresch about “top-line growth opportunities for Mylan over the next several years in a world where exclusive first-to-file opportunities are becoming more rare and the patent cliff for solid

[dose medicine] is waning? . . . How do you grow?” In response, Defendant Bresch touted Mylan’s “operational excellence” as providing Mylan with a key competitive advantage. Defendant Bresch stated, “So, for a company like Mylan, who has prided itself on our operational excellence and making almost 80% of everything we sell, controlling that global supply chain, that brings a real point of leverage and to the business of our ability to do that.”

638. These statements in ¶ 637 were materially false and misleading when made. It was misleading for Defendant Bresch to tout Mylan’s “operational excellence,” while failing to disclose that Mylan’s facilities, including its flagship Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread “testing into compliance.” Mylan also failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed testing and monitoring systems by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards.

639. Additionally, at the June 7, 2016, Goldman Sachs Global Healthcare Conference, an analyst asked Defendant Bresch how Mylan was combating price erosion in the generics market. In response, Defendant Bresch stated that Mylan’s operating capacity gave the Company an advantage in attracting customers, especially as other drug companies failed FDA inspections. Defendant Bresch stated:

It’s always been a volume-driven business, always . . . [T]here’s a much—more of a sense from our customer base that having a reliable global supply chain is important, that they don’t want to have to turn customers away because of products—they’re not able to get their hands on a product. So, if anything, we

continue to see it to be a win-win . . . . But, let's also remember the inspections, the quality side of the house . . . . So, I think you're going to continue to see facilities, drug shortages, facilities shut down that aren't where they need to be to supply the US market.

640. These statements in ¶ 639 were materially false and misleading when made. It was misleading for Defendant Bresch to tout Mylan's vast operational capacity, as a distinct competitive advantage in both retaining customers and taking advantage of market shortages while failing to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. In fact, as investors learned at the end of the Relevant Period, Mylan's operating capacity was severely constrained, and the Company could not produce the same volume of product at the level of quality that the FDA requires and consumers demand.

641. On August 9, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended June 30, 2016 (the "August 9, 2016 8-K"). For the quarter, Mylan reported net income of \$168.40 million, or \$0.33 per diluted share, on revenue of \$2.56 billion, compared to net income of \$167.80 million, or \$0.32 per diluted share, on revenue of \$2.37 billion for the same period in the prior year.

642. In the August 9, 2016 8-K, Mylan stated, in relevant part:

Specialty segment third party net sales were \$402.5 million for the quarter, an increase of 33% when compared to the prior year period. This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®.

[. . .]

Specialty segment third party net sales were \$650.4 million for the six months ended June 30, 2016, an increase of 27% when compared to the prior year period.

This increase was primarily the result of higher unit volumes and the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®.

[. . .]

Gross profit was \$2.08 billion and \$1.84 billion for the six months ended June 30, 2016 and 2015, respectively. Gross margins were 44% and 43% for the six months ended June 30, 2016 and 2015, respectively. Gross margins were positively impacted primarily by new product introductions and favorable Specialty sales, partially offset by higher amortization expense due to acquisitions completed in 2015. Adjusted gross profit was \$2.63 billion and adjusted gross margins were 55% for the six months ended June 30, 2016 compared to adjusted gross profit of \$2.27 billion and adjusted gross margins of 54% in the prior year period. Adjusted gross margins were positively impacted primarily by new product introductions and favorable Specialty sales in the first half of 2016.

643. The statements in ¶¶ 641-642 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, generic drugs, or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

644. On August 9, 2016, Mylan held its second quarter earnings call, attended by Defendants Bresch, Malik, Parks, and others. On that call, Defendant Malik made the following statements:

We continued to see solid performance across our businesses during the second quarter, once again demonstrating that the scale and diversity we have created provides us with the strength, consistency, and resilience to ever-evolving market conditions, further differentiating us from our competitors.

Overall, our generics business delivered third-party net sales of approximately \$2.1 billion for the quarter, an increase of 4% compared to prior-year quarter. In North America, our generics business grew approximately 6% to just over \$1

billion. *Growth came primarily from a significant number of new product introductions, leveraging our strong global platform.*

We launched 18 new products during this quarter. The generic pricing environment was again consistent with our expectations and guidance to you.

(Emphasis added.)

645. These statements in ¶ 644 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

646. On that same August 9, 2016 conference call with investors, Defendant Bresch touted Mylan's "extensive manufacturing operations," stating: "In Mylan's case, we have spent the last decade differentiating, diversifying, and derisking by expanding through organic growth and strategic acquisitions. As a result, we now have extensive manufacturing operations whose technologies range from API to oral solids, to injectables, transdermals, and respiratory expertise."

647. Likewise, on that same call, Defendant Bresch further stated:

The need for a reliable supply is continuing to, I think, again, be a differentiator for Mylan and our ability to meet these global needs in a very reliable—as we've touted before, through sheer hard work that has been put together this last decade is a supply chain that we believe is second to none. And, I think you see some value, continued value, being placed on that by our customers . . . . So I think, it continues to shift towards being a not only a differentiator for us, but a real value driver and growth driver for us, which is why we have the confidence around the stability in the market.

648. The statements in ¶¶ 646-647, were materially false and misleading when made. It was misleading for Defendant Bresch to tout Mylan’s vast operational capacity, as a distinct competitive advantage in retaining customers while failing to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. In fact, as investors learned at the end of the Relevant Period, Mylan’s operating capacity was severely constrained, and the Company could not produce the same volume of product at the level of quality that the FDA requires and consumers demand.

649. On November 9, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company’s financial and operating results for the quarter ended September 30, 2016 (the “November 9, 2016 8-K”). For the quarter, Mylan reported net loss of \$119.8 million, or a loss per share of \$0.23, on revenue of \$3.06 billion.

650. On the November 9, 2016 8-K, Mylan stated, in relevant part:

Specialty segment third party net sales were \$418.7 million for the quarter, a decrease of 4% when compared to the prior year period. This decrease was primarily the result of lower unit volumes due to the timing of wholesaler purchases of the EpiPen® Auto-Injector in anticipation of the authorized generic launch.

[. . .]

Gross profit was \$1.28 billion and \$1.32 billion for the third quarter of 2016 and 2015, respectively. Gross margins were 42% and 49% in the third quarter of 2016 and 2015, respectively. Gross margins were negatively impacted in the current quarter by higher purchase accounting related items, primarily amortization, as a result of the acquisition of Meda and the Topicals Business, and the significant contribution in the prior year period of new products. Adjusted gross profit was \$1.74 billion and adjusted gross margins were 57% for the quarter compared to adjusted gross profit of \$1.58 billion and adjusted gross margins of 58% in the prior year period. Adjusted gross margins were positively impacted by the acquisition of Meda and new products, offset by the significant contribution in the prior year period of new products.

[. . .]

Specialty segment third party net sales were \$1.07 billion for the nine months ended September 30, 2016, an increase of 12% when compared to the prior year period. This increase was primarily the result of the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®, partially offset by lower volumes across the segment.

651. The statements in ¶¶ 649-650 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

652. On November 9, 2016, Mylan held a conference call with investors on which Defendant Malik made the following statements:

Overall, our Generics business delivered third-party net sales of approximately \$2.6 billion for the quarter, an increase of 17% compared to the prior year quarter. Meda contributed \$324 million of these revenues, in-line with our expectations. In North America, our Generics business grew approximately 1% to just about \$1.1 billion on a constant-currency basis. Growth came primarily from our acquisitions of both Meda and the Renaissance topicals business as well as new product introductions. Note that we have a challenging year-over-year comparison this quarter due to significant contribution from the new products in the last year's third quarter, especially Esomeprazole, Lidocaine and Bexarotene. We also experienced increased competition with new entrants on a number of other key products.

The generic pricing environment was again consistent with our expectations and previous guidance.

(Emphasis added.)

653. On November 9, 2016, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter ended September 30, 2016 (the "November 9, 2016 8-K"). For the quarter, Mylan reported net loss of \$119.8 million, or a loss per share of \$0.23, on revenue of \$3.06 billion.

In the November 9, 2016 8-K, Mylan stated, in relevant part:

Specialty segment third party net sales were \$418.7 million for the quarter, a decrease of 4% when compared to the prior year period. This decrease was primarily the result of lower unit volumes due to the timing of wholesaler purchases of the EpiPen® Auto-Injector in anticipation of the authorized generic launch.

[. . .]

Gross profit was \$1.28 billion and \$1.32 billion for the third quarter of 2016 and 2015, respectively. Gross margins were 42% and 49% in the third quarter of 2016 and 2015, respectively. Gross margins were negatively impacted in the current quarter by higher purchase accounting related items, primarily amortization, as a result of the acquisition of Meda and the Topicals Business, and the significant contribution in the prior year period of new products. Adjusted gross profit was \$1.74 billion and adjusted gross margins were 57% for the quarter compared to adjusted gross profit of \$1.58 billion and adjusted gross margins of 58% in the prior year period. Adjusted gross margins were positively impacted by the acquisition of Meda and new products, offset by the significant contribution in the prior year period of new products.

[. . .]

Specialty segment third party net sales were \$1.07 billion for the nine months ended September 30, 2016, an increase of 12% when compared to the prior year period. This increase was primarily the result of the realization of the benefits of customer contract negotiations over the last several quarters related to the EpiPen® Auto-Injector, and higher sales of the Perforomist® Inhalation Solution and ULTIVA®, partially offset by lower volumes across the segment.

654. The statements in ¶¶ 652-653 were misleading because they failed to disclose that Mylan's net income, revenue and gross margins were achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in

anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

655. During the November 9, 2016, conference call Defendant Malik made the following statements:

Overall, our Generics business delivered third-party net sales of approximately \$2.6 billion for the quarter, an increase of 17% compared to the prior year quarter. Meda contributed \$324 million of these revenues, in-line with our expectations. In North America, our Generics business grew approximately 1% to just about \$1.1 billion on a constant-currency basis. Growth came primarily from our acquisitions of both Meda and the Renaissance topicals business as well as new product introductions. Note that we have a challenging year-over-year comparison this quarter due to significant contribution from the new products in the last year's third quarter, especially Esomeprazole, Lidocaine and Bexarotene. We also experienced increased competition with new entrants on a number of other key products. The generic pricing environment was again consistent with our expectations and previous guidance.

(Emphasis added.)

656. These statements in ¶ 655 were misleading because they failed to disclose that Mylan's performance was achieved in significant part because Mylan knowingly had misclassified the EpiPen for the purposes of the MDRP, and accordingly overcharged Medicaid for its EpiPen purchases, and because Mylan had engaged in anticompetitive conduct to exclude competitors of EpiPen from the market and to allocate the market for, and to fix the price of, generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

657. On that same November 9, 2016 conference call, an analyst asked how Mylan was reporting stable revenues when "many of your peers, as you know, this week, have

described a worsening pricing environment, driven by consolidation of buyers.” Defendant Bresch responded that Mylan’s “capacity and capability of supplying” demand gave Mylan a significant competitive advantage:

[T]hat mix, that portfolio, and our capacity and capability of supplying the demands that’s needed out there. It’s what has allowed us to continue to compete in a market, that I would say has always been competitive.

658. In addition, on that same November 9, 2016 conference call, Defendant Mauro claimed that sales in North America had grown due to Mylan’s “broad[] portfolios, consistent execution of new product launches, and being able to reliably supply significant volumes to our customers.” Notably, the North American sales growth was dependent upon the manufacturing output of the Morgantown facility.

659. These statements in ¶¶ 657-658 were materially false and misleading when made. It was misleading for Defendant Bresch and Defendant Mauro to tout Mylan’s vast operational capacity, as a distinct competitive advantage in both retaining customers and taking advantage of market shortages while failing to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. In fact, as investors learned at the end of the Relevant Period, Mylan’s operating capacity was severely constrained, and the Company could not produce the same volume of product at the level of quality that the FDA requires and consumers demand.

## **II. Defendants’ False and Misleading Statements in 2017**

660. On January 11, 2017, Defendants Bresch, Malik, and Parks attended the J.P. Morgan Healthcare Conference on behalf of Mylan. At that conference, an analyst asked Defendants to discuss Mylan’s “position in the market, how you are thinking about pricing and just how do you respond to that skepticism around the sustainability of the price dynamic?” In

response, Defendant Bresch again cited Mylan's operating capacity, specifically highlighting its U.S. production, which was driven by the Morgantown facility. Defendant Bresch stated:

I truly think that it goes back to that our vision and strategy of having this, not just a broad product portfolio but strategically thinking about, if you think about here in the US, everything from the institutional market, the generic market, the prescription market, the OTC market, and if you think about the consolidation that our customers have had, so you look at the channel and the supply chain and to have [the] ability to be that reliable supplier with the capacity to do the kind of the volumes that need to be done across these products, because if I look back last year Mylan was one in every 13 scripts and the United States was filled with the Mylan medicine. That's 21 billion doses. That's more than Pfizer, Merck, J&J, Sanofi, Astra, all combined. So there aren't many that have truly built an integrated global supply chain that can deliver the kind of volume reliably at the same time continuing to invest and bring complex products to the market.

661. These statements in ¶ 660 were materially false and misleading when made.

Defendant Bresch misleadingly attributed Mylan's success in the face of generic price erosion to its broad manufacturing capacity, which allowed the Company to reliably produce industry-leading volume of drugs. It was misleading for Defendant Bresch to tout Mylan's vast operational capacity, as a distinct competitive advantage in both retaining customers and taking advantage of market shortages while failing to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. As investors learned at the end of the Relevant Period, Mylan's operating capacity was severely constrained, and the Company could not produce the same volume of product at the level of quality that the FDA requires and consumers demand.

662. In its March 1, 2017 Annual Report on Form 10-K, Mylan stated, in relevant part:

Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies

that compete based on their clinical characteristics and benefits. Our OTC products face competition from other major pharmaceutical companies and retailers who carry their own private label brands. Our ability to compete in the various OTC markets is affected by several factors, including customer acceptance, reputation, product quality, pricing and the effectiveness of our promotional activities. OTC markets are highly fragmented in terms of product categories and geographic market coverage. Competitive factors in the major markets in which we participate can be summarized as follows:

North America

The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitors include the major manufacturers of brand name and generic pharmaceuticals. The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S. pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products.

663. These statements in ¶ 662 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) Mylan, had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (3) President Rajiv Malik, had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for Doxy DR between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of Doxy DR; (4) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive; and (5) while absent anti-competitive conduct, “the

U.S. pharmaceutical marketplace [was] highly sensitive to price,” the price-fixing cartel of which Mylan was a participant controlled the prices of generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

664. In the same Annual Report filed with the SEC on Form 10-K on March 1, 2017, Defendants repeated the statement, set forth in ¶ 628 above, concerning Mylan’s purported belief that “all of our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for the current operations.” Defendants’ statements were materially false and misleading when made. It was misleading for Defendants to state that Mylan’s “facilities,” including its “significant” Morgantown site, “are in good operating condition, the machinery and equipment are well-maintained,” and that “the facilities are suitable for their intended purposes,” when, in truth, Mylan’s facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations. Far from being “well-maintained” and “suitable for their intended purposes,” both the FDA and Mylan’s own Former Employees reported that Mylan manipulated testing of manufacturing and packaging equipment by “testing into compliance,” falsifying reports, and failing to perform required analyses in the first instance. Moreover, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Further, it was misleading for Defendants to state that Mylan’s facilities “have capacities adequate for the current operations,” when, as Former Employees reported and Mylan privately admitted, the Company’s widespread CGMP failures were a function of the enormous volume of drugs Mylan pushed through its facilities.

665. Additionally, Mylan's 2016 Form 10-K, filed on March 1, 2017, repeated the same misleadingly incomplete "risk disclosure" set forth at ¶ 628 above. That risk disclosure made no mention of the either the Nashik or Morgantown Forms 483 the FDA had already issued to the Company, and, instead, touted the Company's supposed resolution of much of a different warning letter. In that 2016 Form 10-K, Defendants added the following to the "risk disclosure" concerning a warning letter relating to an Indian facility Mylan had acquired from, Agila Specialties another drug company: "On September 12, 2016, the FDA notified us that, based on its evaluation, it appeared we had addressed the issues related to SFF." These statements were materially false and misleading when made. It was misleading for Defendants to state only that Mylan may not "meet regulatory agency standards in the future" and that Mylan "may receive" notices of CGMP violations from regulators, when Mylan's facilities, including its flagship Morgantown facility, were presently rife with serious, repeat CGMP and data integrity violations and Mylan had already privately received multiple warnings from regulators that Morgantown's quality control processes were dangerously deficient and failed to meet regulatory standards. It was additionally misleading for Defendants to tout the Company's supposed resolution of much of the Agila warning letter in the "risk disclosure" Mylan included in its 2016 Form 10-K, while failing to disclose that the Company had been issued two Forms 483, including in connection with the Morgantown facility, citing serious, widespread CGMP and data integrity issues.

666. On April 11, 2017, Mylan issued a statement to news outlets in response to the publication of the Nashik warning letter. Mylan told news media, including Investor's Business Daily:

As FDA standards for our industry continue to evolve, we are dedicated to continually enhancing our systems and processes with a deliberate, thorough approach to assure sustainable quality across our entire network of facilities . . . . The Nashik, India, facility is just one of Mylan's 50 manufacturing sites across

the globe with 24 focused on oral solid doses. Production is ongoing and Mylan doesn't expect any supply issues related to products being manufactured at the India site.

667. These statements in ¶ 666 were materially false and misleading when made. It was misleading for Mylan to state that it was "dedicated to continually enhancing our systems and processes, with a deliberate and thorough approach to ensure sustainable quality across our entire network of facilities," to blame "evolv[ing]" regulatory standards for the issues at the Nashik facility, and to state that Nashik's CGMP deficiencies were an anomaly and that the "facility is just one of Mylan's 50 manufacturing sites." Defendants failed to disclose, among other things, that (i) the FDA had already issued a Form 483 to Mylan identifying the same serious CGMP and data integrity violations cited in the Nashik warning letter, including widespread efforts to evade mandatory product quality testing and standards by "testing into compliance," at the Company's flagship Morgantown facility; (ii) that FDA officials told Defendant Malik directly that Morgantown's failures were "egregious" and raised serious questions about the integrity of the Company's products; (iii) that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company's dangerous CGMP failures; and (iv) that Mylan would have to implement costly remedial measures in order to address the systemic violations at Morgantown.

668. In its May 10, 2017 Current Report on Form 8-K, Mylan stated, in relevant part:

Gross profit was \$1.09 billion and \$907.0 million for the first quarter of 2017 and 2016, respectively. Gross margins were 40% and 41% in the first quarter of 2017 and 2016, respectively. Gross margins were negatively impacted in the current quarter due to increased amortization expense as a result of the acquisitions of Meda and the Topicals Business, lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, partially offset by the contributions from the acquired businesses noted above. Adjusted gross profit was \$1.45 billion and adjusted gross margins were 53% for the first quarter of 2017 compared to adjusted gross profit of \$1.18 billion and adjusted gross margins of 54% in the prior year period. Adjusted gross margins were negatively

impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, partially offset by the contributions from the acquired businesses.

669. These statements in ¶ 668 were misleading because they failed to disclose that Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

670. On May 10, 2017, Mylan held its first quarter earnings call, attended by Defendants Bresch, Malik, Parks, and others. On that call, Defendant Malik reassured investors about the Nashik warning letter and Mylan's facilities generally, stating:

With regards to our operating platform, Mylan has always had a deep and unwavering commitment to quality everywhere we operate. FDA standards for our industry continue to evolve, and this continues to raise the bar for every player in our industry, which is something we very much welcome. For Mylan's part, we are dedicated to continually enhancing our systems and processes, with a deliberate and thorough approach to ensure sustainable quality across our entire network of facilities, working closely with FDA to resolve any issues that come our way. As you are aware, we recently received a warning letter at our Nashik site in India. We are working closely with the FDA to respond to and address the issues raised in the letter as comprehensively and expeditiously as possible.

At the same time, we have successfully completed remediation efforts at the 3 sites acquired from Agila that were under FDA warning letters. The warning letters have been lifted at both SFF and SPD sites and we are pleased with our progress at OTL site, which also was very recently inspected by FDA.

I note that during the quarter, we [had] shifting inspections by various global regulators across our 50 facilities.

671. These statements in ¶ 670 were materially false and misleading when made. It was misleading for Defendant Malik to tout Mylan's "deep and unwavering commitment to quality," to state that Mylan was "dedicated to continually enhancing our systems and processes, with a deliberate and thorough approach to ensure sustainable quality across our entire network

of facilities,” to blame “evolv[ing]” regulatory standards for the issues at the Nashik facility, to state that Nashik’s CGMP deficiencies were an anomaly, and to highlight supposedly positive inspections at all of Mylan’s other facilities. Defendants failed to disclose, among other things, that: (i) the FDA had already issued a Form 483 to Mylan identifying the same serious CGMP and data integrity violations cited in the Nashik warning letter, including widespread efforts to evade mandatory product quality testing and standards by “testing into compliance,” at the Company’s flagship Morgantown facility; (ii) that FDA officials told Defendant Malik directly that Morgantown’s failures were “egregious” and raised serious questions about the integrity of the Company’s products; (iii) that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company’s dangerous CGMP failures; and (iv) that Mylan would have to implement costly remedial measures in order to address the systemic violations at Morgantown.

672. On May 22, 2017, Defendant Parks attended the UBS Global Healthcare Conference on behalf of Mylan. At that conference, an analyst asked Parks whether “you feel like the scale really does matter in negotiating with the consortium [of customers]” and operating capacity would allow Mylan to mitigate price erosion. Defendant Parks answered in the affirmative, stating:

[A]s [customers] get bigger, they want to think about things like availability, service levels, the ability to provide all the different products they need without having to go to 15, 20 different places necessarily. So it doesn’t necessarily take pricing off the table. It actually adds more value to other parts of the discussion when you have scale as well in those types of arrangements.

673. At that same conference, an analyst asked Defendant Parks whether Mylan’s operational capacity was constrained and the Company “need[ed to acquire] anything else.”

Parks stated, “So we’ve been clear that we say we don’t need any large infrastructure plays. We have a lot of the scale that we need.”

674. The statements in ¶¶ 672-673 statements, were materially false and misleading when made. It was misleading for Defendant Parks to tout Mylan’s vast operational capacity, as a distinct competitive advantage in both retaining customers and taking advantage of market shortages while failing to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. In fact, as investors learned at the end of the Relevant Period, Mylan’s operating capacity was severely constrained, and the Company could not produce the same volume of product at the level of quality that the FDA requires and consumers demand.

675. On May 23, 2017, Mylan filed its proxy statement with the SEC on Schedule 14A in connection with the Company’s upcoming annual shareholder meeting, in which the Company touted Mylan’s “high quality manufacturing platform”:

Relentless execution of Mylan’s strategy over the last decade has produced a highly differentiated global company capable of making high quality medicines available to everyone who needs them. Among our many strengths . . . . **Powerful, high quality manufacturing platform:** Our 50 plants around the world manufacture tens of billions of doses of medicine annually, and each site adheres to stringent quality standards, regardless of location.

(bold emphasis in original).

676. These statements in ¶ 675 were materially false and misleading when made. It was misleading for Defendants to tout Mylan’s quality assurance processes and its “high quality manufacturing platform” as key “strengths” of the Company, and to state that “each” of Mylan’s sites “adheres to stringent quality standards, regardless of location,” while failing to disclose that (i) Mylan’s facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality

testing and standards by “testing into compliance”; (ii) that Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown; (iii) that the FDA had issued a lengthy Form 483 to Mylan citing the egregious and widespread CGMP violations at the Morgantown facility; and (iv) that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company’s dangerous CGMP failures.

677. On May 22, 2017, Mylan issued its annual Environmental, Social, and Governance Report (“ESG”) to shareholders. The report quoted Defendant Bresch as stating that Mylan has “an extensive portfolio of more than 7,500 marketed products . . . . We are able to manufacture tens of billions of doses of medicine annually, all to stringent quality standards.”

678. Mylan’s 2017 ESG report further stated:

From a manufacturing and supply chain perspective—typically the most scrutinized area of any pharmaceutical company—Mylan has invested significant resources to ensure quality throughout our value chain. Each of its steps is wrapped in a series of reviews designed to meet or exceed the many regulatory and compliance standards enforced by the dozens of health authorities around the globe that regularly inspect us. The result is an integrated global network capable of providing pharmaceuticals that patients the world over can trust.

679. The statements in ¶ 677-678 statements were materially false and misleading when made. It was misleading for Defendants to tout Mylan’s “significant” investment in quality assurance processes, to state that Mylan had implemented a redundant “series of [quality] reviews” throughout its manufacturing and distribution process, and to state that each of those steps were “designed to meet or exceed the many regulatory and compliance standards” to which Mylan was subject. In truth, far from implementing “a series” of quality reviews at “each step” in the supply chain, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown, failed to investigate known product quality deficiencies, and systematically bypassed the “series of reviews” Defendants touted. As described above,

Mylan evaded CGMP and data integrity regulations by, among other things, falsifying root cause reports, crashing computer systems, altering drug sample sets, and re-testing drugs and equipment until passing results were achieved. Moreover, far from being “designed to meet or exceed” regulatory standards, Mylan’s facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by “testing into compliance.” Indeed, Defendants failed to disclose that the FDA had issued a lengthy Form 483 to Mylan citing the egregious and widespread CGMP violations at the Morgantown facility and that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company’s dangerous CGMP failures.

680. In its August 9, 2017 8-K, Mylan stated, in relevant part:

Gross profit was \$1.23 billion and \$1.17 billion for the second quarter of 2017 and 2016, respectively. Gross margins were 41% and 46% in the second quarter of 2017 and 2016, respectively. Gross margins were negatively impacted in the current quarter by increased amortization expense as a result of the acquisitions of Meda and the Topicals Business by approximately 335 basis points and lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 320 basis points, partially offset by the contributions from the acquired businesses. Adjusted gross profit was \$1.60 billion and adjusted gross margins were 54% for the second quarter of 2017 compared to adjusted gross profit of \$1.45 billion and adjusted gross margins of 56% in the prior year period. Adjusted gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 260 basis points, partially offset by the contributions from acquired Businesses.

681. These statements in ¶ 680 were misleading because they failed to disclose that Mylan’s net income, revenue and gross margins were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of generic

drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

682. On Mylan’s August 9, 2017 earnings call, Defendant Malik again reassured investors about the Nashik warning letter, stating:

With regards to our operating platform, we are in the constructive dialogue with the FDA regarding the warning letter that our Nashik site in India received earlier this year. We are working closely with the agency to comprehensively resolve their 2 observations as expeditiously as possible. The site remains in good standing with other global regulatory entities, including WHO and MHRA.

We are pleased to have had the warning letter from Agila Oncology site lifted during this quarter, joining SFF and SPD in being cleared by FDA.

683. These statements in ¶ 682 were materially false and misleading when made. In purporting to update investors on Mylan’s “operating platform,” it was misleading for Defendant Malik, to state that Mylan was in “constructive dialogue with the FDA” concerning the Nashik warning letter and tout its supposed remediation of CGMP deficiencies at the site Mylan acquired from Agila, while failing to disclose that (i) the FDA had already issued a Form 483 to Mylan identifying the same serious CGMP and data integrity violations cited in the Nashik warning letter, including widespread testing into compliance, at the Company’s flagship Morgantown facility; (ii) that FDA officials told Defendant Malik directly that Morgantown’s failures were “egregious” and raised serious questions about the integrity of the Company’s products; (iii) that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company’s dangerous CGMP failures; and (iv) that Mylan would have to implement costly remedial measures in order to address the systemic violations at Morgantown.

684. On August 9, 2017, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company’s financial and operating results for

the quarter ended June 30, 2017 (the “August 9, 2017 8-K”). For the quarter, Mylan reported net earnings of \$297.0 million, or \$0.55 per diluted share, on revenue of \$2.96 billion.

685. In the August 9, 2017 8-K, Mylan stated, in relevant part:

Gross profit was \$1.23 billion and \$1.17 billion for the second quarter of 2017 and 2016, respectively. Gross margins were 41% and 46% in the second quarter of 2017 and 2016, respectively. Gross margins were negatively impacted in the current quarter by increased amortization expense as a result of the acquisitions of Meda and the Topicals Business by approximately 335 basis points and lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 320 basis points, partially offset by the contributions from the acquired businesses. Adjusted gross profit was \$1.60 billion and adjusted gross margins were 54% for the second quarter of 2017 compared to adjusted gross profit of \$1.45 billion and adjusted gross margins of 56% in the prior year period. Adjusted gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, by approximately 260 basis points, partially offset by the contributions from acquired businesses.

686. The statements in ¶¶ 684-685 were misleading because they failed to disclose that Mylan’s net income, revenue and gross margins were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

687. On August 9, 2017, Mylan held its second quarter earnings call, attended by Defendants Bresch, Malik, and Parks. On that call, a J.P. Morgan analyst asked Defendant Bresch, “should we be thinking about a high single-digit price erosion as something that’s likely to continue for the foreseeable future?” Defendant Bresch responded:

I would say that the consolidation, obviously, you continue to see, I think, we’re down really now to about 3 buying consortiums here in the United States . . . So I think that our ability to partner and leverage our global scale with these global buying consortiums, that we are best positioned to take our entire product portfolio across the globe and be one of the best partners out there.

688. On November 6, 2017, Mylan held its third quarter earnings call, attended by Defendants Bresch, Malik, and Parks. On that call, Defendants were asked whether Mylan would spend money to acquire additional assets. Defendant Bresch replied that Mylan had all the operational capacity it needed. She stated, “We have been pretty staunch and since the Meda acquisition that we really had the assets that we needed to leverage this global commercial platform and have that infrastructure in place.”

689. The statements in ¶¶ 687-689 were materially false and misleading when made. It was misleading for Defendant Bresch to tout Mylan’s vast operational capacity, as a distinct competitive advantage in both retaining customers and taking advantage of market shortages while failing to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. In fact, as investors learned at the end of the Relevant Period, Mylan’s operating capacity was severely constrained, and the Company could not produce the same volume of product at the level of quality that the FDA requires and consumers demand.

### **III. Defendants’ False and Misleading Statements in 2018**

690. On January 9, 2018, Defendants Malik, Bresch, and Parks attended the J.P. Morgan Healthcare Conference on behalf of Mylan. At that conference, Defendants Bresch and Malik both touted the competitive advantages Mylan’s broad generics portfolio gave the Company and told investors that Mylan did not need to cede this advantage by reducing, or “rationalizing,” that portfolio. In response to an analyst question about Mylan’s competitors “rationalizing portfolios,” Defendant Malik stated:

[W]e have already seen some pressure around drug shortages, around the commodities because everybody is trying to look at where you make money, where you don’t make money. And the first one which stand out over there is those lossmaking products. And we have a broad portfolio, we have a broad

offering. We have a vertically integrated platform, which is tuned up to deliver to this market.

691. Likewise, at the January 9, 2018 conference, an analyst asked Defendants about the impact of price erosion on Mylan's business. Again, Defendant Bresch emphasized that Mylan's vast operating capacity and broad portfolio were allowing the Company to mitigate the impact of erosion better than its competitors. Defendant Bresch stated:

[T]he larger [customers have] become, the larger their needs have become. And I don't think there's very many players out there today that can actually fulfill the breadth of the product and the reliability that they need. And secondly, I think it's—you can't look at all companies created equally that they're negotiating with, because again, I think, where Mylan has differentiated itself is, one, having that broad base, that portfolio, the capacity to truly meet the supply that's needed and the investing in these complex products. And all of that gives us a seat at the table perhaps a bit differently than our peers

692. Similarly, at that same conference, an analyst asked whether Mylan needed to reduce its generics portfolio in order to limit its exposure "loss-making products." Defendant Bresch, specifically referencing the Morgantown facility, responded, and Defendant Malik agreed:

[W]e're running facilities that are making 15 billion tablets and capsules in a year . . . . And what you could be making less money on one day, you could be making more on the next, given the dynamics in the supply chain. So for us, as others are having financial constraints or having to make perhaps short-term decisions because they have to, I think we have found ourselves in a position to really take into consideration again that long-term view.

693. Later, at that same investor conference, in response to another analyst question about how Mylan would resist price erosion "if nobody cuts capacity." Defendant Bresch responded:

I think there are players dropping out of the market. I think we've seen it . . . . So what my point was, as companies are rationalizing, we're able to kind of be patient and make sure we're making that right longer-term decision versus a very

knee jerk reaction to what's happening in the market at the moment. As you know, that can change very quickly.

\* \* \*

So as other companies are forced to rationalize or look at things, absolutely we're looking at that as an opportunity. And from the facilities we have here in the U.S., Europe and around the world to be able to strategically be able to absorb those different volumes is what we've really been set up to do.

694. The statements in ¶¶ 690-693 were materially false and misleading when made. It was misleading for Defendants Bresch and Malik to tout Mylan's vast operational capacity, as a distinct competitive advantage in both retaining customers and taking advantage of market shortages while failing to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. As investors learned at the end of the Relevant Period, Mylan's operating capacity was severely constrained, and the Company could not produce the same volume of product at the level of quality that the FDA requires and consumers demand.

695. On February 28, 2018, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the year ended December 31, 2017 and Fourth Quarter 2017 (the "February 28, 2018 8-K"). For the year, Mylan reported revenue of \$11.91 billion, and for the quarter, Mylan reported revenue of \$3.24 billion.

696. In the February 28, 2018 8-K, Mylan stated, in relevant part:

In 2017, we delivered an 8% increase in total revenues year over year, as strong performances by our Europe and Rest of World segments more than offset ongoing volatility across the healthcare industry in the U.S. marketplace.

[. . .]

Gross profit was \$1.29 billion and \$1.34 billion for the fourth quarter of 2017 and 2016, respectively. Gross margins were 40% and 41% in the fourth quarter of

2017 and 2016, respectively. Adjusted gross profit was \$1.80 billion and adjusted gross margins were 55% for the fourth quarter of 2017 compared to adjusted gross profit of \$1.85 billion and adjusted gross margins of 57% in the prior year period. Gross margins and adjusted gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, partially offset by contributions from new products.

697. The statements in ¶¶ 695-696 were misleading because they failed to disclose that Mylan's financial results were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

698. In its March 1, 2018 Annual Report on Form 10-K, Mylan stated, in relevant part:

Competition

Our primary competitors include other generic companies (both major multinational generic drug companies and various local generic drug companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent expirations and other statutory expirations. In the branded space, key competitors are generally other branded drug companies that compete based on their clinical characteristics and benefits. Our OTC products face competition from other major pharmaceutical companies and retailers who carry their own private label brands. Our ability to compete in the various OTC markets is affected by several factors, including customer acceptance, reputation, product quality, pricing and the effectiveness of our promotional activities. OTC markets are highly fragmented in terms of product categories and geographic market coverage.

Competitive factors in the major markets in which we participate can be summarized as follows:

North America

The U.S. pharmaceutical industry is very competitive. Our competitors vary depending upon therapeutic areas and product categories. Primary competitor include the major manufacturers of brand name and generic pharmaceuticals. The primary means of competition are innovation and development, timely FDA approval, manufacturing capabilities, product quality, marketing, portfolio size, customer service, reputation and price. The environment of the U.S.

pharmaceutical marketplace is highly sensitive to price. To compete effectively, we rely on cost-effective manufacturing processes to meet the rapidly changing needs of our customers around a reliable, high quality supply of generic pharmaceutical products.

699. The statements in ¶ 698 were misleading because they failed to disclose that: (1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) among the primary means by which Mylan competed was by anticompetitive means to eliminate competitors of EpiPen, including, *inter alia*, by offering massive rebates to commercial insurance companies and PBMs contingent upon excluding Sanofi's Auvi-Q from the market; (3) Mylan had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (4) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive; and (5) while absent anti-competitive conduct, "the U.S. pharmaceutical marketplace [was] highly sensitive to price," the price-fixing cartel of which Mylan was a participant controlled the prices of generic drugs for which demand was relatively inelastic, allowing the price-fixing cartel to increase prices for those drugs exponentially without generating a proportionate drop in demand.

700. In its Annual Report filed with the SEC on Form 10-K on March 1, 2018, Defendants also repeated the statement set forth in ¶ 628 above. These statements were materially false and misleading when made. It was misleading for Defendants to state that Mylan's "facilities," including its "significant" Morgantown site, "are in good operating condition, the machinery and equipment are well-maintained," and that "the facilities are suitable for their intended purposes," when, in truth, Mylan's facilities, including its flagship

Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by “testing into compliance.” Indeed, as both the FDA and Mylan’s own Former Employees reported, Mylan manipulated testing of manufacturing and packaging equipment by “testing into compliance,” falsifying reports, and failing to perform required analyses in the first instance. Moreover, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Further, it was misleading for Defendants to state that Mylan’s facilities “have capacities adequate for the current operations,” when, as Former Employees reported and Mylan privately admitted, the Company’s widespread CGMP failures were a function of the enormous volume of drugs Mylan pushed through its facilities.

701. Additionally, in Mylan’s SEC-mandated “Risk Disclosures” in the Form 10-K the Company filed on March 1, 2018, Defendants repeated the same misleadingly incomplete picture of Mylan’s CGMP compliance and product quality risk set forth at ¶ 628 above. These statements were materially false and misleading when made. It was misleading for Defendants to state only that Mylan may not “meet regulatory agency standards in the future” and that Mylan “may receive” notices of CGMP violations from regulators, when Mylan’s facilities, including its flagship Morgantown facility, were presently rife with serious, repeat CGMP and data integrity violations. Moreover, at the time Defendants issued this Risk Disclosure, Mylan had already privately received multiple warnings from regulators that Morgantown’s quality control processes were dangerously deficient and failed to meet regulatory standards.

702. On March 5, 2018, Defendant Parks attended the Raymond James Institutional Investor Conference, on behalf of Mylan. At that conference, an analyst asked Defendant Parks,

to “talk about any potential product portfolio rationalization” in light of the “large-scale rationalization” by “a lot of the major players.” Defendant Parks responded:

[W]e have not talked about rationalization at all in the U.S. space. We’ve heard some of our peers and competitors talk about rationalization in the U.S. generic space . . . . And I think some of these larger customers value the fact that you can bring to them more today than 5 years ago the ability to supply them with a broader range of products because they, in turn, have a commitment to their own customers to meet time and delivery and availability of product

703. On March 14, 2018, Defendant Bresch attended the Barclays Global Healthcare Conference on behalf of Mylan. In response to an analyst question, Defendant Bresch touted Mylan’s “operational excellence” and “ability to manufacture high-quality, high-volume products” as key competitive advantages that would allow Mylan to capitalize on supply shortages:

So I think the credibility of our science, our portfolio, our ability, our operational excellence, the ability to manufacture high-quality, high-volume products around the globe, I think has been a hallmark of Mylan. And our ability to be that reliable supplier in what has continued to be a consolidated marketplace . . . . And I think Teva and Sandoz are focused very differently right now, and we see opportunity in that. Because I think there’s opportunity for us to pick up supply.

704. The statements in ¶¶ 702-703 were materially false and misleading when made. It was misleading for Defendants Bresch and Parks to tout Mylan’s vast operational capacity, as a distinct competitive advantage in both retaining customers and taking advantage of market shortages while failing to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. In truth, and as the Company privately admitted, Mylan’s manufacturing capacity at its flagship Morgantown facility—the bulwark of its U.S. generics business—was severely constrained. The overwhelming output demands Defendants placed on the plant rendered it impossible for Mylan

to comply with its regulatory obligations and to perform the rigorous quality testing it assured investors it was performing on “all products, start to finish.

705. On May 9, 2018, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company’s financial and operating results for the quarter ended March 31, 2018 (the “May 9, 2018 8-K”). For the quarter, Mylan reported revenue of \$2.68 billion.

In the May 9, 2018 8-K, Mylan stated, in relevant part:

Net sales from existing products on a constant currency basis decreased \$286.2 million primarily as a result of lower volumes, and to a lesser extent, pricing, which were partially offset by new product introductions of \$102.6 million. Sales were also negatively impacted by the adoption of new accounting standards of a net impact of approximately \$17.7 million. Mylan’s total revenues were favorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan’s subsidiaries in the European Union, India, the United Kingdom, Japan, and Australia

706. These statements in ¶ 706 were misleading because they failed to disclose that Mylan’s financial results were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of, generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

707. On April 20, 2018, Mylan issued a statement to reporters announcing that it was laying off 15% of the employees at Morgantown. Mylan stated:

As the industry has changed and regulatory expectations have continued to evolve, we’ve realized that our Morgantown plant needed to be rightsized to be less complex. The right-sizing is consistent with discussions we are having with the U.S. Food and Drug Administration and is necessary in order to position the site as best we can for continued operations.

708. These statements in ¶ 707 were materially false and misleading when made. It was misleading for Defendants to state that Mylan was “right-sizing” the workforce at the

Morgantown plant simply because management “realized” the facility needed “to be less complex,” while failing to disclose that, in reality, the “right-sizing” was driven by the FDA’s issuance—for the second time in two years—of a Form 483 citing Morgantown’s serious, repeat CGMP and data integrity violations. As a result, the Company had halted production at the facility, significantly reduced the “broad” portfolio of generic drugs Defendants had touted throughout the Relevant Period, was already in the process of recalling numerous drugs manufactured at Morgantown, and was forced to implement expensive remedial measures greatly increasing operating costs.

709. On May 10, 2018, Mylan issued its annual ESG report to shareholders. As the 2018 ESG report explains, its “[c]ontent is based on relevant ESG considerations and addresses topics in which our stakeholders have expressed interest.” In a section of the 2018 report entitled “Maintaining Quality In Everything We Do,” Defendants touted Mylan’s quality control processes and manufacturing standards, including Mylan’s Quality Council’s effective oversight of these critical functions. Defendants stated:

For us, quality begins with product development, as we work to ensure an acceptable safety and efficacy profile for every drug we hope to market, and it extends through every step of the production process, from making or sourcing raw materials to producing finished dosage forms . . . . Mylan has global systems and processes in place to provide our people with the foundation and tools needed to maintain an effective quality management system . . . . Our Quality Council program provides management with clear, quantitative data, including that of key performance indicators. It also tracks and analyzes quality trends, review inspection results and identifies potential areas for employee training.

\* \* \*

In addition, we have an extensive, formal internal-audit program to help monitor activity at our facilities, as well as that of our suppliers and other partners.

710. Likewise, in a section of that same 2018 ESG report entitled “Ensuring Quality and Product Safety,” Mylan stated that it performed 42 “quality and GMP audits at [its] own facilities.”

711. These statements in ¶¶ 709-710 were materially false and misleading when made. It was materially misleading for Defendants to tout Mylan’s quality assurance processes, its rigorous product quality standards, the oversight provided by its “Quality Council program,” and the numerous “quality and GMP audits” conducted pursuant to the Company’s “extensive, formal internal-audit program.” In truth, Mylan’s facilities, including its flagship Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by “testing into compliance.” Moreover, Defendants’ statements failed to disclose that the FDA had already issued Mylan two Forms 483 citing serious and pervasive CGMP violations at Morgantown in as many years. Contrary to Defendants’ statements touting Mylan’s “Quality Council program,” the FDA specifically found that the Quality Council had failed to appropriately apply and enforce CGMP standards consistent with both FDA regulations and Mylan’s own operating requirements, citing “numerous instances of a lack of appropriate oversight.” Further, Defendants failed to disclose that, as a result of the FDA’s inspections, the Company had halted production at the Morgantown facility, significantly reduced the “broad” portfolio of generic drugs Defendants had touted throughout the Relevant Period, was already in the process of recalling numerous drugs manufactured at Morgantown, and was forced to implement expensive remedial measures greatly increasing operating costs.

712. On May 10, 2018, Mylan filed its first quarter Form 10-Q, which incorporated by reference Mylan’s misleadingly incomplete SEC-mandated “Risk Disclosures” set forth at ¶ 628

above. Mylan's May 10, 2018 Form 10-Q stated, "There have been no material changes in the Company's risk factors from those disclosed in Mylan's Annual Report on Form 10-K for the year ended December 31, 2017, as amended." Mylan's risk disclosure made no mention of either the 2016 or 2018 Morgantown Forms 483 the FDA had already issued to the Company.

713. These statements in ¶ 712 were materially false and misleading when made. It was misleading for Defendants to state only that Mylan may not "meet regulatory agency standards in the future" and that Mylan "may receive" notices of CGMP violations from regulators, when Mylan's facilities, including its flagship Morgantown facility, were presently rife with serious, repeat CGMP and data integrity violations. Moreover, Defendants failed to disclose that Mylan had already privately received multiple warnings from regulators that Morgantown's quality control processes were dangerously deficient and failed to meet regulatory standards. In fact, by this time, Mylan had already received two Form 483's in just two years citing egregious and widespread CGMP violations at the Morgantown facility, and, as a result, Mylan had halted all production at the facility, had dramatically reduced the Company's portfolio of generic drugs, had recalled numerous drugs manufactured at the Morgantown facility, and had been forced to begin implementing drastic remedial measures.

714. On June 13, 2018, Defendant Bresch attended the Goldman Sachs Global Healthcare Conference on behalf of Mylan. An analyst asked Defendant Bresch, "[H]ow do you feel about where we are with just the whole U.S. generic drug landscape?" Defendant Bresch responded:

I couldn't be more excited about not only our portfolio—our current portfolio before even getting to the pipeline about the reliability, our ability to supply, our ability to be patient and be able to take advantage of the opportunities in the marketplace because of some other companies being forced to take certain actions . . . [O]ur ability to supply has really allowed us to continue to step up and be able to take advantage of that in the marketplace.

715. These statements in ¶ 714 made after the Company had started significant undisclosed remediation efforts to address the 2018 Form 483, were materially false and misleading when made. It was misleading for Defendant Bresch to tout Mylan’s vast operational capacity, “our ability to supply, our ability to be patient and be able to take advantage of the opportunities in the marketplace” as key competitive advantages and to state that Mylan’s “ability to supply has really allowed us to continue to step up and be able to take advantage of that in the marketplace,” while failing to disclose that Mylan had already been forced to halt production at the Morgantown facility, significantly reduce its generics portfolio, recall numerous drugs manufactured at Morgantown, and implement expensive remedial measures. Indeed, as the Company privately admitted, Mylan’s manufacturing capacity at its flagship Morgantown facility—the bulwark of its U.S. generics business—was severely constrained. The overwhelming output demands Defendants placed on the plant rendered it impossible for Mylan to comply with its regulatory obligations and perform the rigorous quality testing it assured investors it was performing on “all products, start to finish.”

716. Shortly before market-close on June 27, 2018, Bloomberg issued a brief news alert reporting that the FDA had concluded a four-week inspection of the Morgantown facility in April 2018 and had issued a Form 483 citing multiple CGMP violations. Under pressure to respond and in an effort to spin the story to quell investor concern, Mylan issued a press release on June 28, 2018 that downplayed the Morgantown inspection and failed to disclose key, highly material facts to investors. The press release stated:

Mylan is committed to maintaining the highest quality manufacturing standards at its facilities around the world. In support of this commitment, Mylan’s plants are regularly inspected by health authorities to ensure compliance for the various markets we serve. The U.S. Food and Drug Administration (FDA) recently completed an inspection at Mylan’s plant in Morgantown and made observations

through a Form 483. The company has submitted a comprehensive response to the Agency and committed to a robust improvement plan.

We remain confident in the quality, safety and efficacy of our drug products, including those in distribution, and we continue to manufacture and ship product from the site. Mylan will continue to maintain a close dialogue with the Agency and is fully committed to working with FDA to address its observations.

717. These statements in ¶ 716 were materially false and misleading when made. It was misleading for Defendants to tout Mylan’s “commit[ment] to maintaining the highest quality manufacturing standards at its facilities around the world,” to state that it remained “confident in the quality, safety and efficacy of our drug products, including those in distribution,” and to claim that “we continue to manufacture and ship product from” Morgantown. In truth, the seriousness and pervasiveness of the CGMP violations the FDA identified at Morgantown had already forced Mylan to (i) halt manufacturing at the facility; (ii) significantly reduce the Company’s “broad” portfolio of generic drugs that Defendants touted throughout the Relevant Period; (iii) recall numerous drugs manufactured at Morgantown; and (iv) implement expensive remedial measures greatly increasing operating costs.

718. On August 8, 2018, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company’s financial and operating results for the quarter ended March 31, 2018 (the “August 8, 2018 8-K”). For the quarter, Mylan reported revenue of \$2.68 billion.

719. In the August 8, 2018 8-K, Mylan stated, in relevant part:

Total revenues were \$2.81 billion....

[. . .]

The decrease in total revenues included lower net sales in the North America segment of 22%. This decrease was partially offset by net sales increases in the Europe segment of 4%, and in the Rest of World segment of 10%. The overall decrease in total revenues was primarily driven by a decrease in net sales from

existing products. Net sales from existing products, partially offset by new product launches, decreased on a constant currency basis by approximately \$222.0 million primarily as a result of lower volumes, and to a lesser extent, pricing. [. . .] Mylan's total revenues were favorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan's subsidiaries in the European Union, which was partially offset by the unfavorable impact from changes in the Indian Rupee.

720. The statements in ¶¶ 718-719 were misleading because they failed to disclose that Mylan's financial results were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

721. On August 8, 2018, during Mylan's earnings call following its announcement that the 2018 Form 483 had forced them to undertake a remediation and restructuring program at Morgantown, Defendant Parks stated:

[W]e believe that . . . effectively, the part of our business that we want to bring back, we're comfortable that, that remediation and restructuring is going to be completely effective for Morgantown. And therefore, our profitable business will come back into the portfolio and we've made some choices around certain products as we simplify and make the Morgantown facility less complex. So overall, this impact is temporary and we believe that our profitability levels are sustainable.

722. On this same call, Defendant Malik further falsely stated that the Morgantown restructuring "was not triggered just by this FDA inspection. It was part of . . . this year's plan actually to right size it. Because we have observed that it will be very difficult for us to manage this sort of complexity which Morgantown has, which 20 billion doses, with evolving FDA expectations."

723. On this same call, Defendant Bresch stated:

[W]e are continuing to totally up that facility and doing it as quickly as we possibly can. So certainly, we are hopeful, I think as Rajiv said, that through

2018, that we will be seeing that continued turnaround and us continuing to be able to rebring volume back up to where we said we were bringing it back up to, which is obviously streamlined from where the facility has been historically. So kind of that rightsizing and remediation is all happening simultaneously.

724. The statements in ¶¶ 721-724 were false and misleading when made. It was misleading for Defendants to state that the Morgantown restructuring “was not triggered just by this FDA inspection,” that the Morgantown “right-sizing” was simply as “part of . . . this year’s plan,” and that the remediation was driven by “evolving FDA expectations” while failing to disclose that the “right-sizing” was driven in significant part by the FDA’s issuance—for the second time in two years—of a Form 483 citing Morgantown’s serious, repeat CGMP and data integrity violations. It was also misleading for Defendants to claim that the impact of the remediation program on Mylan’s business would be “temporary” and the Mylan’s “profitability levels are sustainable,” while failing to disclose that, in truth, Mylan’s remediation entailed a severe and permanent reduction in the Morgantown’s production levels and in the Company’s generics portfolio. Moreover, Mylan’s extensive remediation was not only causing severe reductions in production levels, but also significant increases in operating costs.

725. On November 5, 2018, Mylan held its earnings call for the third quarter of 2018 and further falsely minimized the news of the Morgantown restructuring and its dramatic impact on Mylan’s bottom line. Specifically, Defendant Bresch stated, “Let me start by celebrating the broad contribution, in fact, of our Morgantown facility’s restructuring and remediation, which began in the second quarter of this year on our North American business as this may have been misunderstood by the investment community.” Defendant Bresch continued, “These actions have led to a temporary disruption in supply of certain products for our customers and reduced volume in North America generic sales. However, the value related to the

rationalized product is not proportionate to the reduced volumes of those commoditized products.”

726. These statements in ¶ 725 were materially false and misleading when made. It was misleading for Defendants to claim that the “negative financial impact [of the remediation program] on the business” was “largely behind us” when, these facts were continuing to significantly impact Mylan’s business. Mylan’s CGMP and data integrity violations at Morgantown were far more widespread and had a far greater impact on the Company’s business than Defendants admitted. In truth, Mylan’s remediation entailed a severe and permanent reduction in the Morgantown’s production levels and in the Company’s generics portfolio. Moreover, Mylan’s extensive remediation was not only causing severe reductions in production levels, but also significant increases in operating costs.

#### **IV. Defendants’ False and Misleading Statements in 2019**

727. In a January 31, 2019 Bloomberg article, Defendants responded to allegations of CGMP and data integrity failures at Mylan’s plants, including the practice of “testing into compliance.” Defendants stated that Mylan manufactures all of its products at all of its facilities “under stringent processes, procedures and rigorous testing designed to ensure that they meet the highest standards for quality, safety and efficacy. Any explicit or implicit suggestion that Mylan employees circumvented data and quality systems that jeopardized the quality of the medications we manufacture—for time pressures or any other reason—is simply false.”

728. These statements in ¶ 727 were materially false and misleading when made. It was misleading for Defendants to state that Mylan’s manufacturing occurs “under stringent processes, procedures, and rigorous testing” and that the Company’s protocols were “designed to ensure that they meet the highest standards for quality, safety and efficacy.” In truth, and as FDA

investigators had discovered, Mylan’s facilities, including its flagship Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by “testing into compliance.” Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed quality monitoring systems by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, as discussed above, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards. The seriousness and pervasiveness of the CGMP violations the FDA identified at Morgantown had already forced Mylan to (i) halt manufacturing at the facility, (ii) significantly reduce the Company’s “broad” portfolio of generic drugs that Defendants touted throughout the Relevant Period, (iii) recall numerous drugs manufactured at Morgantown, and (iv) implement expensive remedial measures greatly increasing operating costs.

729. On February 26, 2019, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company’s financial and operating results for the fourth quarter and the year ended December 31, 2018 (the “February 26, 2019 8-K”).

730. In the February 26, 2019 8-K, Mylan stated, in relevant part:

U.S. GAAP gross profit for the three months ended December 31, 2018 was \$1.02 billion and U.S. GAAP gross margins were 33%. For the three months ended December 31, 2017, U.S. GAAP gross profit was \$1.29 billion and U.S. GAAP gross margins were 40%. U.S. GAAP gross margins were negatively impacted by approximately 270 basis points related to the incremental amortization from product acquisitions and intangible asset impairment charges and by approximately 240 basis points as a result of incremental manufacturing expenses, site remediation expenses and incremental restructuring charges incurred during the current quarter principally as a result of the activities at the Company’s Morgantown plant. U.S. GAAP gross margins were also negatively impacted as a

result of lower gross profit from the sales of existing products partially offset by gross margins on new product introductions primarily in North America. Adjusted gross profit was \$1.68 billion and adjusted gross margins were 55% for the three months ended December 31, 2018 compared to adjusted gross profit of \$1.80 billion and adjusted gross margins of 55% in the prior year period. Adjusted gross margins were negatively impacted by lower gross profit from sales of existing products partially offset by gross margins on new product introductions primarily in North America.

731. The statements in ¶¶ 729-730 were misleading because they failed to disclose that Mylan's financial results were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of, generic drugs (including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

732. In its February 27, 2019 Annual Report on Form 10-K, Mylan stated, in relevant part:

We face vigorous competition that threatens the commercial acceptance and pricing of our products.

The pharmaceutical industry is highly competitive. We face competition from other pharmaceutical manufacturers globally, some of whom are significantly larger than we are. Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including but not limited to the possibility that they may have:

- proprietary processes or delivery systems;
- larger or more productive R&D and marketing staff;
- larger or more efficient production capabilities in a particular therapeutic area;
- more experience in preclinical testing and human clinical trials;
- more products; or
- more experience in developing new drugs and greater financial resources, particularly with regard to manufacturers of branded products.

We also face increasing competition from lower-cost generic products and other branded products.

[. . .]

Competitors' products may also be safer, more effective, more effectively marketed or sold, or have lower prices or better performance features than ours. We cannot predict with certainty the timing or impact of competitors' products.

733. These statements in ¶ 732 were misleading because they failed to disclose that:

(1) Mylan also competed in ways highly likely, at a minimum, to raise regulatory scrutiny; (2) Mylan, including President Rajiv Malik, had engaged in collusive anticompetitive activity with other drug companies, including (a) allocating the markets for generic drugs between Mylan and those companies and agreeing with those companies not to compete with each other for certain customers or in certain markets, and (b) colluding with other drug companies to fix the prices of generic drugs; (3) as a result of this anticompetitive activity, the markets for generic drugs sold by Mylan were not competitive.

734. On May 7, 2019, Mylan issued a press release and filed a Current Report on Form 8-K with the SEC, announcing certain of the Company's financial and operating results for the quarter and ended March 31, 2019 (the "May 7, 2019 8-K").

735. In the May 7, 2019 8-K, Mylan stated, in relevant part:

U.S. GAAP gross profit was \$805.2 million and \$984.3 million for the three months ended March 31, 2019 and 2018, respectively. U.S. GAAP gross margins were 32% and 37% for the three months ended March 31, 2019 and 2018, respectively. U.S. GAAP gross margins were negatively impacted by approximately 60 basis points related to the incremental amortization from product acquisitions. U.S. GAAP gross margins were also negatively affected by approximately 280 basis points as a result of incremental manufacturing expenses, site remediation expenses and incremental restructuring charges incurred during the current period principally as a result of the activities at the Company's Morgantown plant. In addition, U.S. GAAP gross margins were negatively impacted as a result of lower gross profit for sales of existing products partially offset by the impact from new product sales, primarily in North America.

736. The statements in ¶¶ 734-735 were misleading because they failed to disclose that Mylan's financial results were achieved in significant part because Mylan had engaged in anticompetitive conduct to allocate the market for, and to fix the price of generic drugs

(including through price-fixing activity in which Defendants Malik and Nesta personally participated), or at a minimum, had competed in ways highly likely to raise regulatory scrutiny.

**V. Defendants' Additional False and Misleading Statements Throughout the Relevant Period**

737. Throughout the Relevant Period, Defendants repeatedly certified that they had established effective disclosure controls and procedures for Mylan.

738. For example, along with the 2016 Annual Report, Defendant Bresch provided a certification, pursuant to Section 302 of SOX, concerning Mylan's internal controls. Defendant Bresch stated:

I have reviewed this Form 10-K of Mylan, N.V.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

...

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) . . . for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

...

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation . . . .

739. Defendants Bresch and Parks provided substantially identical certifications pursuant to Section 302 of SOX for Mylan's 2017 Annual Report.

740. Defendant Bresch provided substantially identical certifications pursuant to Section 302 of SOX for Mylan’s Quarterly Report for the First Quarter of 2016.

741. Defendants Bresch and Parks provided substantially identical certifications pursuant to Section 302 of SOX for Mylan’s Quarterly Report for the Second Quarter of 2016.

742. The statements in ¶¶ 737-741 were materially false and misleading because Mylan did not have effective disclosure controls and procedures between 2016-2019.

743. Indeed, any internal controls that Mylan did have in place were woefully deficient to assure that Defendants could not mislead investors about the misclassification of the EpiPen and Mylan’s anticompetitive conduct with respect to the EpiPen.

744. The material weaknesses in Mylan’s control environment were highlighted by its entry into the Corporate Integrity Agreement (“CIA”).

745. The CIA required Mylan to make certain enhancements to its Corporate Compliance Program and to implement certain reporting requirements. The CIA required Mylan to, among other things:

(a) Appoint a senior member of management as an independent Compliance Officer who reports directly to the CEO. The Compliance Officer was to be responsible for “developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements”; “making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Mylan Inc.”; and “monitoring the day-to-day compliance activities engaged in by Mylan as well as for any reporting obligations created under this CIA.”

(b) Create a Compliance Committee comprised of the Compliance Officer and members of senior management who have responsibility for, among others, the audit and operations departments.

(c) Pass an annual Board resolution that states the following: “The Board of Directors (or a committee thereof) has made a reasonable inquiry into the operation of Mylan’s Compliance Program during the preceding twelve-month period including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Mylan has implemented an effective Compliance Program

to meet Federal health care program requirements and the obligations of the Corporate Integrity Agreement.”

(d) Have Mylan’s CFO, Head of Commercial Finance – North America, Head of Government Reporting, Head of Finance, Global Integrated Services – North America, and Director, Accounts Receivable sign annual certifications that their respective business units are compliant with applicable healthcare program requirements and with the obligations of the CIA.

(e) Develop and implement written policies and procedures regarding the operation of its Compliance Program. The CIA requires that, “[a]t a minimum, the Policies and Procedures shall address appropriate ways to conduct Government Pricing Functions in compliance with all applicable Federal health care program requirements. This includes (a) gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS) and/or the State Medicaid Programs in connection with the Medicaid Drug Rebate Program, the Medicare program, and as otherwise required by Federal or state government requirements and directives; and (b) the appropriate classification of drugs as Single Source, Innovator Multiple Source, or Non-Innovator Multiple Source drugs for purposes of the Medicaid Drug Rebate Program.”

(f) Develop a written training plan “that outlines the steps Mylan will take to ensure that: (a) all Covered Persons receive adequate training regarding Mylan’s CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute, and (b) all Relevant Covered Persons receive adequate training regarding: (i) Mylan’s systems and processes relating to Government Pricing Functions; (ii) all applicable Federal health care program requirements relating to Government Pricing Functions; and (iii) Mylan’s systems for gathering relevant data and calculating, verifying, and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Drug Rebate Program, the Medicare Program, or any other Federal or state government price reporting requirement.”

(g) Subject each member of the Board to at least two hours of training that addresses “the corporate governance responsibilities of board members and the responsibilities of board members with respect to review and oversight of the Compliance Program.”

(h) Engage an Independent Review Organization to report on Mylan’s classification of drugs under the MDRP. (i) Develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the drugs that are paid for by Medicaid.

(j) Establish a disclosure program that “includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command any identified issues or questions associated with Mylan’s policies, conduct, practices, or procedures with respect to a Federal health care program requirement believed by the individual to be a potential violation of criminal, civil, or administrative law.” “Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted.”

(k) Provide written notice to the Office of Inspector General – within thirty days of discovery – “of any ongoing investigation or legal proceeding known to Mylan conducted or brought by a governmental entity or its agents involving an allegation that Mylan has committed a crime or has engaged in fraudulent activities.” (l) Provide written notice to the Office of Inspector General – within thirty days of determining that a “Reportable Event” has occurred – of “a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program requirements for which penalties or exclusion may be authorized.”

746. Mylan’s agreement to undertake these improvements to its internal controls highlights the significant deficiencies in its disclosure controls and procedures that needed to be addressed as of the August of 2017 (when Mylan entered into the CIA). The fact that Mylan had to implement these measures, in August of 2017 demonstrates, at the very least, the falsity of Defendants’ prior certifications concerning the purported effectiveness of Mylan’s disclosure controls and procedures.

747. Throughout the Relevant Period, Defendants also made public statements on Mylan’s website touting the Company’s rigorous product quality standards. Each of these statements were materially false and misleading because, as discussed above, Mylan’s facilities, including its flagship Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by “testing into compliance.” Therefore, as the FDA warned Mylan no later than 2016,

the Company’s “[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity,” and “[t]here is a failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed,” among other serious CGMP deficiencies, as discussed above. Indeed, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown.

748. Throughout the Relevant Period, on a webpage entitled “Quality,” Defendants stated:

Mylan applies one global quality standard across our facilities, and across our product line . . . regardless of market. At Mylan, whether it’s a medication for millions or for a handful of people our priorities are to meet or exceed industry standards. Because there’s nothing generic about our standards. Our internal teams conduct reviews of all products, start to finish. No matter where in the world they are made. In fact, we championed a law that empowers the FDA to biennially inspect all manufacturing facilities around the world that supply the U.S. market.

(ellipses in original)

749. These statements in ¶ 745-748 were materially false and misleading when made. It was misleading for Defendants to tout Mylan’s quality assurance processes and its rigorous product quality standards, and to state that Mylan’s “internal teams conduct reviews of all products, start to finish” and the Company “uses advanced testing and monitoring systems to assure product adheres to testing acceptance criteria” when Mylan’s facilities were rife with serious CGMP and data integrity violations, including widespread “testing into compliance.” Further, far from “conduct[ing] reviews of all products, start to finish,” Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and

anomalies, and systematically bypassed testing and monitoring systems by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, as discussed above, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards.

750. Throughout the Relevant Period, Defendants made public statements on Mylan's website touting the Company's "One Global Quality" standard, the Company's commitment to "meet or exceed industry standards, and its "ongoing reviews to ensure quality and integrity of products, start to finish." On a webpage entitled "How We Make Generic Medicines At Mylan," Defendants stated:

*One Global Quality Standard.* Whether it's a medication for millions or for a handful of people, our priorities are to meet or exceed industry standards. Our own teams conduct ongoing reviews to ensure quality and integrity of products, start to finish, and to continually improve for optimal quality and consistency.

751. These statements in ¶ 750 were materially false and misleading when made. In truth, as detailed above, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread "testing into compliance." Far from conducting "ongoing reviews to ensure quality and integrity of products, start to finish," Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed quality monitoring systems by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, as discussed above, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards.

752. Throughout the Relevant Period, Defendants made public statements on Mylan’s website touting the Company’s “advanced” product quality monitoring systems, which Defendants stated exceeded CGMP requirements and were used to “reject” and “remove” OOS products. On a webpage entitled “How We Make Generic Medicines At Mylan,” Defendants stated:

*Advanced Monitoring Systems.* Although not required, Mylan utilizes state-of-the-art monitoring systems that can automatically evaluate and reject a product that does not meet specifications. This advanced technology is used to automatically remove a defective product from production or packaging lines.

753. These statements in ¶ 752 were materially false and misleading when made. In truth, as detailed above, Mylan’s facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread “testing into compliance.” Far from actually “us[ing]” its monitoring systems “to automatically remove a defective product from production or packaging lines,” Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed its “state-of-the-art monitoring systems” by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, as discussed above, Mylan retested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards.

754. Throughout the Relevant Period, Defendants made public statements on Mylan’s website that Mylan performed product quality testing to ensure the Company had “proof of purity and potency” before drugs were marketed to the public. On a webpage entitled “How We Make Generic Medicines At Mylan,” Defendants stated:

Proof of Purity and Potency. Mylan assures product potency, purity and drug release through expiration date by testing the stability of our products at specific intervals.

755. These statements in ¶ 754 were materially false and misleading when made. In truth, as detailed above, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread "testing into compliance." In fact, the FDA specifically warned Mylan no later than 2016, the Company's "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity," and "[t]here is a failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed." Further, in the 2016 Form 483, the FDA specifically warned Mylan that its stability testing in connection with numerous drugs and drug products was "conducted using non-validated and non-verified analytical test methods" and cited numerous instances of inadequate investigation into failed stability results. Likewise, former Mylan employees reported widespread testing into compliance in connection with stability testing. For instance, as Katherine Eban reported, a former Mylan chemist stated that when drugs failed stability testing, "[y]ou play with the parameters so impurities don't show up." Moreover, as discussed above, Mylan failed to perform even nominal quality testing, including stability testing, on the vast majority of the drugs manufactured at Morgantown.

756. Throughout the Relevant Period, Defendants made public statements on Mylan's website that Mylan "used an established testing and verification process to" test the quality of its pharmaceutical ingredients. On a webpage entitled "How We Make Generic Medicines At Mylan," Defendants stated:

Protection Against Defects. Quality begins at step one. Mylan uses an established testing and verification process to ensure the suitability of active ingredients used in our medicines.

757. These statements in ¶ 756 were materially false and misleading when made. In truth, as detailed above, Mylan’s facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread “testing into compliance.” Indeed, in its 2016 Form 483, the FDA specifically warned Mylan that its stability testing in connection with APIs were “conducted using non-validated and non-verified analytical test methods.” Moreover, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown.

### **LOSS CAUSATION**

758. Defendants’ wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs.

759. Throughout the Relevant Period, the price of the Company’s securities was artificially inflated and/or maintained at an artificially high level as a result of Defendants’ materially false and misleading statements and omissions identified herein.

760. The price of the Company’s securities significantly declined when the misrepresentations made to the market, and/or the information and risks alleged herein to have been concealed from the market, and/or the effects thereof, materialized and/or were revealed, causing investors’ losses.

761. Mylan’s failure to disclose the fraudulent activity artificially inflated the value of Mylan’s shares and/or maintained those shares at an artificially high level, and the revelation and/or materialization of this information and/or the risks concealed by Mylan’s fraud resulted in substantial losses to Plaintiffs.

**I. August 19-24, 2016**

762. On August 17, 2016, at 6:42PM EST, NBC News published an article titled, “EpiPen Price Hike Has Parents of Kids with Allergies Scrambling Ahead of School Year” highlighting the price increases in the EpiPen over the prior years.<sup>50</sup>

763. On August 19, 2016 at 3:41PM EST, NBC News published an article titled “Martin Shkreli Weighs in on EpiPen Scandal, Calls Drug Makers ‘Vultures’” stating, “A growing chorus is calling on the Mylan pharmaceutical company to justify its price hikes on EpiPens.”<sup>51</sup>

764. On August 20, 2016, Senator Amy Klobuchar of Minnesota, the top Democrat on the Judiciary Committee’s antitrust subcommittee, publicly called for a hearing to investigate “the enormous increase in the price of EpiPens.”<sup>52</sup>

765. On August 22, 2016, Senator Charles Grassley of Iowa, Chairman of the Senate Judiciary Committee, sent a letter to Defendant Bresch, which was published the same day.<sup>53</sup> The letter stated that Mr. Grassley was “concerned that the substantial price increase could limit access to a much-needed medication” and requested additional information on the price increases.

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<sup>50</sup> Ben Popken, EpiPen Price Hike Has Parents of Kids With Allergies Scrambling Ahead of School Year, NBC News (Aug. 17, 2016), *available at* <http://www.nbcnews.com/business/economy/epipen-price-hike-has-parents-kids-allergies-scrambling-ahead-school-n633071>.

<sup>51</sup> Ben Popken, Martin Shkreli Weighs in on EpiPen Scandal, Calls Drug Makers ‘Vultures,’ NBC News (Aug. 19, 2016), *available at* <http://www.nbcnews.com/business/consumer/martin-shkreli-weighs-epipen-scandal-calls-drugmakers-vultures-n634451>.

<sup>52</sup> Amy Klobuchar, Klobuchar Calls for Judiciary Hearing and Investigation Into at Least 400 Percent Increase of EpiPen Packs (Aug. 20, 2016), *available at* <https://www.klobuchar.senate.gov/public/index.cfm/2016/8/klobuchar-calls-for-judiciary-hearing-and-investigation-into-at-least-400-percent-increase-of-epipen-packs>.

<sup>53</sup> Letter from Charles E. Grassley, U.S. Senator, to Heather Bresch, CEO Mylan N.V. (Aug. 22, 2016), *available at* [https://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-22%20CEG%20to%20Mylan%20\(EpiPen\).pdf](https://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-22%20CEG%20to%20Mylan%20(EpiPen).pdf).

Also on August 22, 2016, Senator Klobuchar sent a letter to the FTC requesting an investigation into Mylan’s price increase on the EpiPen.<sup>54</sup>

766. On August 24, 2016, The New York Times published an article titled, “Mylan Raised EpiPen’s Price Before the Expected Arrival of a Generic,” in which it stated that the company’s history of pricing the product highlights a common tactic in the drug industry: sharply raising prices in the years just before a generic competitor reaches the market.<sup>55</sup>

767. On this news and other similar stories, risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan’s share price fell \$6.17, or 12.51% between August 19 and August 24, 2016 to close at \$43.15 on August 24, 2016.<sup>56</sup> Specifically, Mylan’s share price fell \$0.66, or 1.34% on August 19, \$0.76, or 1.56% on August 22, \$2.28, or 4.76% on August 23 and \$2.47, or 5.41% on August 24, 2016.

## II. September 2, 2016

768. On September 2, 2016, Inside Health Policy published an article stating that the CMS had “informed Mylan that [the Company] incorrectly classified EpiPen as a generic under

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<sup>54</sup> Amy Klobuchar, Klobuchar Calls for FTC Investigation of Mylan Pharmaceuticals for Possible Antitrust Violations in Light of Dramatic Price Increase of EpiPen Packs, News Release (Aug. 22, 2016), *available at* <https://www.klobuchar.senate.gov/public/index.cfm/news-releases?ID=3F5E034C-82A8-4AB9-BAA8-CBD78932FBED>.

<sup>55</sup> Andrew Pollack, Mylan Raised EpiPen’s Price Before the Expected Arrival of a Generic, The New York Times (Aug. 24, 2016), *available at* [https://www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html?\\_r=0](https://www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html?_r=0).

<sup>56</sup> All quoted price drops in this complaint refer to drops in the share price of Mylan on NASDAQ. Substantially similar drops in the share price of Mylan on TASE occurred on or around the dates referenced in this section, and for the same or substantially the same reasons the drops in the share price of Mylan on NASDAQ occurred.

the Medicaid rebate program, which caused financial consequences for federal and state governments by reducing the amount of quarterly rebates Mylan owed for its product.”<sup>57</sup>

769. On this news, risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan’s share price fell \$1.95, or 4.65%, to close at \$39.97 on September 2, 2016.

### **III. October 5, 2016**

770. On October 5, 2016, Bloomberg reported that CMS had issued a letter stating that Mylan had for years overcharged Medicaid to buy the Company’s EpiPen shot, despite being told that the Company needed to provide larger discounts under the law. The CMS letter stated that from 2011 to 2015, the U.S. Medicaid health program spent approximately \$797 million on EpiPens, including rebates of roughly 13%, rather than the discount of 23.1% that the U.S. should have received. The letter stated that the government had previously “expressly told Mylan that the [EpiPen] product is incorrectly classified.”<sup>58</sup>

771. On this news, risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan’s share price fell \$1.19, or 3.13%, to close at \$36.84 on October 6, 2016.

### **IV. October 7, 2016**

772. On October 7, 2016, Evercore ISI released an analysis suggesting that Mylan may have overcharged the national Medicaid system over \$707 million on its purchases of EpiPen

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<sup>57</sup> Inside Health Policy, CMS Tells Mylan It Incorrectly Classified EpiPen To Pay Lower Medicaid Rebates, Lawmakers Upset (Sept. 2, 2016), available at <https://insidehealthpolicy.com/daily-news/cms-tells-mylan-it-incorrectly-classified-epipen-pay-lower-medicaid-rebates-lawmakers#:~:text=CMS%20has%20informed%20Mylan%20it,2>.

<sup>58</sup> Robert Langreth, Mylan Accused by U.S. of Overcharging Medicaid for EpiPen, Bloomberg News (Oct. 5, 2016), available at <https://www.bloomberg.com/news/articles/2016-10-05/mylan-overcharged-u-s-on-epipen-for-years-u-s-says>.

between 2011 to 2015.<sup>59</sup> On the same day, Mylan announced that it had agreed to pay \$465 million to settle the DOJ's investigation into Mylan's classification of the EpiPen for the purposes of the MDRP.<sup>60</sup>

773. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$0.90, or 2.44%, to close at \$35.94 on October 7, 2016.

#### **V. October 12, 2016**

774. On October 11, 2016, at 6:40PM EST, CNBC reported that an Evercore ISI analyst had concluded that the alleged settlement agreement Mylan announced on October 7, 2016 "ha[d] a \$120 million question attached to it," since Medicaid was projected to purchase \$120 million in EpiPens during a six month grace period provided for under the alleged settlement agreement, and the details of the rebate terms governing those six months were not made public.<sup>61</sup>

775. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$1.24, or 3.24%, to close at \$37.07 on October 12, 2016.

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<sup>59</sup> Dan Managan, Underpayments on EpiPen Rebates to Medicaid Could Top \$700 million, CNBC News (Oct. 7, 2016), *available at* <http://www.cnbc.com/2016/10/07/underpayments-on-epipen-rebates-to-medicaid-could-top-700-million-dollars.html>.

<sup>60</sup> Press Release, Mylan Agrees to Settlement on Medicaid Rebate Classification for EpiPen® Auto-Injector (Oct. 7, 2016), *available at* <http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector>

<sup>61</sup> Dan Mangan, Mylan's Grace Period for EpiPen Rebates Could Cost Medicaid up to \$120 Million, CNBC News (Oct. 11, 2016), *available at* <https://www.cnbc.com/2016/10/11/mylans-grace-period-for-epipen-rebates-could-cost-medicaid-up-to-120-million.html>

**VI. November 3, 2016**

776. On November 3, 2016, Bloomberg News reported that U.S. DOJ prosecutors were bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion.<sup>62</sup>

777. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result, Mylan's share price fell \$2.53, or 6.9% to close at \$34.14 on November 3, 2016.

**VII. November 10, 2016**

778. On November 10, 2016, reports emerged that an Evercore SIS analyst had estimated that Mylan could face liability between \$380 million and \$770 million under the DOJ's price collusion investigation, and that the DOJ could impose industry-wide fines in excess of \$1 billion.<sup>63</sup>

779. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result, Mylan's share price dropped \$0.64, or 1.64% to close at \$38.28 on November 10, 2016.

**VIII. December 14, 2016**

780. On December 14, 2016, Bloomberg News reported that two executives, Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals in Eatontown, Monmouth County, and Jason T. Malek, Heritage's former senior vice president of commercial operations,

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<sup>62</sup> David McLaughlin and Caroline Chen, U.S. Charges in Generic-Drug Probe to Be Filed by Year-End, Bloomberg News (Nov. 3, 2016), available at <https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end>.

<sup>63</sup> See, e.g., Eric Sanowsky, DOJ's Price-Fixing Investigation Could Lead to Sizable Liabilities, Analyst Says, FiercePharma (Nov. 10, 2016), available at <https://www.fiercepharma.com/pharma/doj-s-price-fixing-investigation-could-lead-to-sizable-liabilities-analyst-says>.

were “preparing to plead guilty to price-fixing charges,” in a scheme that involved unnamed executives from Mylan.<sup>64</sup>

781. On this news, risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan’s share price dropped \$0.61, or 1.6% to close at \$37.69 on December 14, 2016.

#### **IX. January 10, 2017**

782. On January 10, 2017, The Philadelphia Inquirer reported that “Jeffrey A. Glazer, ex-chief executive and chairman of Heritage Pharmaceuticals in Eatontown, Monmouth County, and Jason T. Malek, the company’s former senior vice president of commercial operations, admitted to conspiring to manipulate prices of a popular antibiotic and a diabetes medication between April 2013 and December 2015.”<sup>65</sup>

783. On this news, risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result between January 10, 2017 and January 12, 2017, Mylan’s share price dropped \$2.18 or 5.6% to close at \$36.77 on January 12, 2017.

#### **X. January 30, 2017**

784. On January 30, 2017, Bloomberg News reported that Mylan had received a request for information from the FTC regarding whether Mylan had engaged in anticompetitive activity relating to the EpiPen.<sup>66</sup>

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<sup>64</sup> Tom Schoenberg, David McLaughlin and Sophia Pearson, U.S. Generic Drug Probe Seen Expanding After Guilty Please, Bloomberg News (Dec. 14, 2016), available at <https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe>.

<sup>65</sup> Jeremy Roebuck, Ex-N.J. Pharma Execs Admit to Fixing Generic Drug Prices, The Philadelphia Inquirer (Jan. 10, 2017), available at [http://www.philly.com/philly/news/new\\_jersey/20170110\\_Ex-N\\_J\\_pharma\\_execs\\_admit\\_to\\_fixing\\_generic\\_drug\\_prices.html](http://www.philly.com/philly/news/new_jersey/20170110_Ex-N_J_pharma_execs_admit_to_fixing_generic_drug_prices.html).

<sup>66</sup> David McLaughlin, Sara Forden and Jared Hopkins, Mylan Faces U.S. Antitrust Investigation on EpiPen, 272

785. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$0.32, or 0.87% to close at \$36.34 on January 30, 2017.

#### **XI. October 31, 2017**

786. On October 31, 2017, the Attorney General of the State of Connecticut issued a press release on behalf of 46 state attorneys general in which he announced that the group would be filing an amended complaint in their antitrust action against Mylan and attached the proposed amended complaint. The amended complaint contained extensive new allegations detailing how Mylan participated in a wide-ranging price-fixing conspiracy, and for the first time named Defendant Malik, Mylan's President and Executive Director, as an individual defendant for his direct participation in the conspiracy. The amended complaint also contained additional details regarding the conspiracy between Mylan and other drug companies to allocate the market and fix the price of generic drugs, and contained new allegations of express agreements between Mylan and other drug companies to fix the prices of additional generic drugs. The new allegations were based on an extensive investigation by the attorneys general, including review of internal Mylan emails (many of which were cited and quoted in the allegations), telephone records, text messages and other corporate documents.

787. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$2.53, or 6.62%, to close at \$35.71 on October 31, 2017.

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Bloomberg News, at 1 (Jan. 30, 2017), *available at* <https://www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices>.

**XII. June 27, 2018**

788. *Bloomberg* reported that, in the spring of 2018, the FDA conducted a five-week inspection of the Morgantown facility and issued a Form 483 listing 13 significant deficiencies in Morgantown's operations.

789. On this news, Mylan's share price fell \$1.12, or 2.99%, to close at \$36.33 on June 27, 2018.

**XIII. August 8, 2018**

790. Mylan disclosed that, following the FDA's inspection, the Company undertook a restructuring and remediation program at Morgantown that included discontinuation of certain products and negatively impacted production, supply, and operations. Mylan also disclosed approximately \$87 million in expenses related to the Morgantown restructuring and remediation and a \$2.8 billion decline in total revenue.

791. On this news, Mylan's share price fell \$2.62, or 6.68% to close at \$36.61 on August 9, 2018

**XIV. February 26, 2019**

792. Mylan disclosed a 5% and 4% decline of total quarterly and yearly revenues; a 16% decline in North American segment net sales, driven by the Morgantown remediation; the discontinuation of 250 products; and \$258 million in remediation costs.

793. On this news, Mylan's share price fell \$4.61, or 15.06% to close at \$26.01 on February 27, 2019.

**XV. May 7, 2019**

794. Mylan disclosed losses for the first quarter of 2019 due to costs associated with the Morgantown remediation, including 7% and 15% declines in revenue and earnings-per-share.

795. On this news, Mylan’s share price fell \$6.73, or 23.81% to close at \$21.53 on May 7, 2019.

#### **XVI. May 10, 2019**

796. On May 10, 2019, the attorneys general of 44 states filed a lawsuit after trading hours alleging extensive new allegations that Mylan and other generic drug companies had engaged in a massive conspiracy to allocate the market for, and fix the prices of, over 100 generic drugs. The complaint detailed compelling evidence, collected by the state attorneys general through an extensive investigation, that Mylan had conspired with competitors to allocate the markets and fix the prices for numerous generic drugs. This evidence included details about the extensive communications between Mylan and its co-conspirators. The complaint made clear that Mylan and its co-conspirators’ anticompetitive activity was not limited to a handful of drugs, but rather was so widespread as to be the standard procedure by which these companies operated in the marketplace: each company was entitled to its “fair share” of the market, and the companies agreed to “play nice in the sandbox.”

797. On this news, risks or truth concealed by, or effects associated with, Mylan’s fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan’s share price fell \$2.09, or 9.43% to close at \$20.08 on May 13, 2019.

#### **XVII. May 28, 2019**

798. On May 28, 2019, UBS published a report titled, “Mylan Inc., Expanded Alleged Price Fixing Creates Another Overhang—Reiterate Neutral; TP to \$23.” In this report, UBS provided details regarding the potential exposure the Company faced in the 2017 and 2019 antitrust suits by the state attorneys general. Based on this analysis, UBS lowered its twelve-month price target from \$31.00 to \$23.00.

799. On this news, risks or truth concealed by, or effects associated with, Mylan's fraud and anticompetitive conduct were revealed, or materialized, and as a result Mylan's share price fell \$1.11, or 5.85%, to close at \$17.87 on May 28, 2019.

#### **ADDITIONAL SCIENTER ALLEGATIONS**

800. As alleged in this Complaint, numerous facts give rise to the strong inference that, throughout the Relevant Period, the Defendants knew or recklessly disregarded that their statements and omissions were materially false and misleading when made. The information in this section summarizes certain of the allegations—that are set forth more fully above—that detail the Defendants' scienter.

801. First, the Individual Defendants acted with scienter with respect to the materially false and misleading statements, and omissions of material fact, set forth above because they knew, or at the very least recklessly disregarded, that those statements were false when made. As the most senior executives of Mylan during the Relevant Period, the Individual Defendants' scienter is imputable to Mylan.

802. Defendant Nesta was, at all relevant times, a central player in Mylan's market allocation and price-fixing scheme. He was very senior at Mylan—he reported to Matthew Erick, who was at all relevant times President, North America for Mylan Pharmaceuticals. Matthew Erick reported directly to CEO Bresch. Accordingly, Defendant Nesta was only one reporting level removed from the CEO, and was sufficiently senior at Mylan that his knowledge and actions may be imputed to the corporation.

803. During the Relevant Period, Defendant Bresch served as CEO of Mylan, Defendant Malik served as President of Mylan, Defendant Parks served as CFO of Mylan, and Defendant Mauro served as COO of Mylan. Defendant Bresch, by virtue of her responsibilities

and activities as CEO of the Company, Malik, by virtue of his responsibilities and activities as President, Parks, by virtue of his responsibilities and activities as CFO, and Mauro by virtue of his responsibilities and activities as COO, were privy to, and participated in the fraudulent conduct described in this Complaint.

804. Because Mylan's sales of the EpiPen were part of Mylan's core business, the Individual Defendants would have had robust knowledge of significant aspects of those sales, including the Medicaid rebates.

805. Because Mylan's sales of EpiPen were part of Mylan's core business, the Individual Defendants, and through them Mylan, would have had robust knowledge of significant aspects of those sales, and knew about or recklessly disregarded Mylan's misclassification of the EpiPen for the purposes of the MDRP, and Mylan's massive, unprecedented, anticompetitive rebates to third-party payors expressly conditioned on their excluding Sanofi's Auvi-Q epinephrine autoinjector from their formularies, and related conduct.

806. Defendants Bresch and Parks likewise repeatedly attested to their understanding of the rule for classifying drugs for the purposes of the MDRP, and understood this rule to require products, like the EpiPen, that were marketed under NDAs to be classified as brand drugs. In SEC filings throughout the Relevant Period, each of Bresch and Parks, certified that the following statement was accurate and not misleading:

The required rebate is currently 13% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under NDAs, up from 11% in prior years. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23% (up from 15%) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period.

807. This statement makes clear that the Individual Defendants knew or recklessly disregarded the simple rule for the proper classification of the EpiPen for the purposes of the

MDRP, knew the financial consequences of that classification for Medicaid and Mylan, and yet continued to classify the EpiPen as if it were marketed under an ANDA and subject to only a 13% rebate. The Individual Defendants each knew or recklessly disregarded that they were marketing their single most important drug, the EpiPen, as a brand name drug under an NDA, rather than as a generic drug under an ANDA, and so knew that under the simple rule they certified to be accurate and not misleading, the EpiPen was misclassified.

808. The Individual Defendants likewise knew or recklessly disregarded Mylan's misclassification of the EpiPen because CMS repeatedly informed Mylan that Mylan was misclassifying the EpiPen for purposes of the MDRP, and because in November 2014, the DOJ had opened an investigation into "whether EpiPen Auto-Injector was properly classified with the [CMS] as a non-innovator drug under the applicable definition in the Medicaid Rebate Statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs."

809. Prior to making the material misrepresentations described above, the Individual Defendants also knew about, or recklessly disregarded, the DOJ's investigation into Mylan's classification of the EpiPen. The November 2014 DOJ subpoena to Mylan raised serious concerns about a significant part of Mylan's core business. Mylan did not simply ignore that subpoena; rather, by Mylan's own admission, it "complied with various information requests received from the DOJ pursuant to the subpoena." However, Defendants failed to disclose the existence of this investigation to investors for several years.

810. The fact that – just two days after CMS's disclosure to Congress that it had "on multiple occasions . . . expressly told Mylan that the product is incorrectly classified" – Mylan settled with the DOJ for almost half a billion dollars is further evidence of the Individual Defendants' scienter.

811. Defendants Bresch and Parks also attested to their robust knowledge of Mylan's sales and pricing activity. Specifically, they signed certifications in Mylan's periodic SEC filings pursuant to SOX. In each of these certifications, Defendants Bresch and Parks stated that the information contained in Mylan's periodic reports was accurate and not misleading. These attestations required knowledge of Mylan's financial statements and the bases of these financial statements, including the bases for Mylan's statements of its sales, revenue and drug pricing. These attestations also required knowledge of Mylan's statements of risk factors and whether those risks had materialized.

812. As stated above, according to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, CW1 confirmed that Defendant Bresch, as CEO, and Defendant Parks, as CFO, each knew of and approved all material pricing decisions made by the Company. The Third Amended Consolidated Complaint alleges that CW1 started working at Mylan in 2010 as Director of Costing and later became Director of Production Planning before leaving Mylan in October 2015. CW1 worked in Mylan's Morgantown, West Virginia facility, which at the time was the largest pharmaceutical manufacturing plant in the world. CW1 was part of several groups that met regularly to assess costs. In CW1's role as Director of Costing, CW1 worked directly with Mylan's former CFO, John Sheehan. CW1 also attended company-wide meetings that were led by Defendant Bresch and concerned company initiatives. CW1 also worked with Defendant Malik's predecessor as President, Defendant Mauro, on costing decisions.

813. As set forth in the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, CW1 stated that pricing decisions at Mylan occurred frequently and involved all of Mylan's top executives. “[Price] was always a topic.” CW1 stated in particular that the CEO and CFO of Mylan reviewed any price adjustments and had the last word on

pricing decisions for Mylan’s drugs. According to CW1, Defendant Bresch discussed price adjustments to Mylan’s drugs frequently. “Especially if it was [pricing of] a specific product, everything went up through the top. We would have end of quarter and month meetings where we discussed pricing.” For example, “[w]hen we were looking at one product we were making for the government, an anthrax antibiotic, everyone, all the way to the president and CEO, discussed what price to sell it at.” CW1 understood the “anthrax antibiotic” in question to be doxycycline.

814. The numerous investigations and legal actions into Mylan’s misclassification of the EpiPen and price fixing further evidence Mylan’s scienter. In addition to multiple, ongoing investigations by the DOJ, SEC, CMS, and the United States Congress, the attorneys general of more than forty states, in multiple investigations, have uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States, by among others, Mylan. Mylan senior executives participated consciously and willingly in the anticompetitive conduct at issue in these investigations.

815. That Mylan and the Individual Defendants knew about the Company’s market allocation and price-fixing activity alleged in this Complaint is likewise clear because one of the executives at Mylan who directly participated in this activity, Defendant James Nesta, Vice President of National Accounts at Mylan, was frequently in direct contact with the highest-level executives at the Company, including Defendant Mauro.

816. According to the Third Amended Consolidated Complaint in the S.D.N.Y. Mylan Class Action, a second confidential witness, CW2, provided this information on Defendant Nesta’s position at Mylan. CW2 worked at Mylan from January 2004 to June 2007 as an

Associate, Pricing and Contracts and then from July 2007 to November 2017 as a Key Account Manager in the Dallas/Fort Worth area. CW2 last reported to Heather Paton, Mylan's head of sales. During CW2's tenure at Mylan, CW2 attended meetings with Defendant Nesta, the Vice President of National Accounts. CW2 said that Defendant Nesta reported to Matt Erick, who was President of North America at Mylan.

817. Defendant Nesta routinely attended conferences with these highest-level Mylan executives as part of a small group, which included the executives named below and Nesta. These conferences included at least the following:

- 2013 National Association of Chain Drug Stores (NACDS) Annual Meeting, attended with then-President of Mylan, Joe Duda, and Mylan's then-President of North America, Defendant Mauro;
- 2013 National Association of Chain Drug Stores (NACDS) Total Store Expo, attended with Duda;
- 2014 Healthcare Distribution Management Association (HDMA) Sixth Annual CEO Roundtable Fundraiser, attended with Duda and Defendant Mauro;
- 2014 National Association of Chain Drug Stores (NACDS) Annual Meeting, attended with Duda and Defendant Mauro;
- 2015 Healthcare Distribution Management Association (HDMA) Annual CEO Roundtable Fundraiser, attended with Defendant Mauro;
- 2015 Healthcare Distribution Management Association (HDMA) Annual Board and membership meeting, attended with Defendant Mauro; and
- 2016 National Association of Chain Drug Stores (NACDS) Annual Meeting, attended with Defendant Mauro.

818. That Mylan and Defendant Parks agreed to settle the DOJ's investigation into Mylan's misclassification of EpiPen for purposes of the MDRP for at least \$465 million also evidences scienter.

819. That Mylan and the Individual Defendants knew or recklessly disregarded that Mylan offered massive, unprecedented rebates to third-party payors expressly conditioned on their not including Sanofi's Auvi-Q in their formularies evidences scienter.

820. Mylan's President during the Relevant Period, Defendant Malik, sold 25,000 shares of Mylan stock on June 9, 2017 (about 3% of his Mylan holdings) for proceeds of \$1,000,000, and Mylan's COO during the Relevant Period, Defendant Mauro, sold 10,000 shares of Mylan stock on June 9, 2017 (about 6.6% of his Mylan holdings) for proceeds of \$400,000. These sales evidence scienter.

821. That the prices of the Price-Fixed Drugs increased immediately following meetings of members of generic drug companies (attended by Mylan executives, including Defendant Bresch) during which the companies, including Mylan, colluded to fix generic drug prices, evidences scienter.

822. Second, Defendants received numerous direct warnings, both before and during the Relevant Period that Mylan's quality assurance processes at the Morgantown facility were dangerously deficient and that the site was rife with serious, widespread CGMP and data integrity failures. For instance, as alleged above, the FDA privately sent Mylan a Form 483 in November 2016 detailing numerous egregious CGMP and data integrity violations at Morgantown that directly contradicted Defendants' public statements. Among other things, the FDA's 2016 Form 483 warned Defendants that Mylan:

- Routinely “tested into compliance” by repeatedly re-testing drug products that had failed quality testing in order to achieve passing results without any legitimate investigation into the cause of the initial failure;
- Repeatedly misstated investigative findings;
- Altered drug samples
- “Improperly invalidated” reports of defects and failing quality testing results; and
- Engaged in a host of suspect data practices, including “pre-injecting” batch samples, designed to avoid recording failing quality testing results and triggering costly production delays and recalls.

823. Again, as alleged above, and as Defendants were well-aware, these CGMP and data integrity violation, including Mylan’s improper practice of testing into compliance, were extremely serious and required remediation. This remediation historically entailed severe disruptions to production and increased operating costs for extended periods.

824. Even after the FDA privately issued Mylan the 2016 Form 483, Defendants continued to receive clear warnings from the FDA that Morgantown suffered from severe quality control issues. For instance, in April 2017, Defendant Malik attended a private meeting with the FDA, at which agency officials directly told him that they were “stunned” by Mylan’s “egregious” violations, which they said led the agency to question whether the Company was being “transparent at all of its sites.” Indeed, Defendant Malik only prevented the FDA from issuing a warning letter that would publicly reveal Morgantown’s CGMP deficiencies by committing Mylan to extensive remediation, which, as alleged above, the Company failed to implement. Indeed, according to the Amended Complaint in the W.D. Pa. Mylan Class Action, FE6 reported that Defendant Malik not only failed to allocate additional resources to Morgantown to finance the extensive remediation that the plant clearly required, but FE6 insisted on cuts to the facility’s budget.

825. Moreover, during the Relevant Period, Mylan was forced to recall numerous drug products manufactured at Morgantown, including drugs cited in the FDA’s 2016 Form 483. Between the start of the Relevant Period and the FDA’s April 2018 inspection, recall notices were issued for at least 15 different drugs and dosages manufactured at the Morgantown plant, including drugs referenced in the 2016 Form 483, for reasons—such as evidence of cross-contamination and OOS manufacture—that made clear to Defendants that the CGMP failures about which they had been privately warned in the 2016 Form 483 remained widespread and continued to affect production at the facility.

826. In the spring of 2018, Defendants received another clear and unambiguous warning that Morgantown was rife with serious CGMP and data integrity failures. On April 12, 2018, following an inspection prompted by a whistleblower report of continued fraud at Mylan, the FDA issued yet another scathing Form 483 to Mylan citing the same egregious CGMP and data integrity violations about which the Defendants Bresch, Malik, Parks, and other members of Mylan’s senior leadership had been repeatedly warned, including in Morgantown’s 2016 Form 483. Among other things, the FDA found that Mylan’s improper practice of invalidating failing results and retesting drug products without adequate investigation was still widespread. As a result of the FDA’s findings, Defendants were forced to halt production at Morgantown, dramatically reduce Mylan’s generics portfolio, and implement an extensive CGMP remediation program. Yet, even at this point, Defendants continued to tout the Company’s robust assurance processes and its vast operating capacity and conceal the truth from investors.

827. Indeed, Defendants only disclosed the FDA’s 2018 Form 483 when forced to do so, after Bloomberg issued a short blurb reporting on the FDA’s inspection. Again, however, Defendants failed to disclose the significant production disruptions or increased operating costs

roiling the Company’s operations, and, instead, issued misleading soothing statements to spin the adverse news and quell investor concern.

828. Even before the start of the Relevant Period, Defendants received numerous warnings of pervasive data integrity violations at Morgantown. For instance, in 2009, the Pittsburgh PostGazette reported that employees routinely engaged in a host of improper practices designed to evade the FDA’s quality regulations, including “crashing files.” As alleged above, Defendants not only vigorously and falsely denied the newspaper’s allegations, but also sued the Post-Gazette in order to silence further reporting on these issues.

829. Third, that Defendants were charged with ensuring the adequacy of Mylan’s quality assurance processes and regularly received information about the state of the Company’s CGMP compliance supports an inference of scienter. As alleged above, Mylan submitted an internal “SOP”—standard operating procedure—to the FDA. Mylan’s SOP provided that “Senior Management,” together with the Company’s Quality Council, was responsible for “ensuring” Mylan’s quality control and CGMP compliance by, among other things, closely monitoring detailed information on these subjects it received from a variety of oversight organs and programs. Specifically, Mylan’s SOP states that Mylan’s Quality Council “along with Senior Management” must “ensure continuing suitability and effectiveness of quality systems through governance including but not limited to Trending Review Board, Annual Product Review, Self-Inspection, and Quality Site Council.”

830. In fact, as alleged above, Mylan touted management’s close oversight of the Company’s quality control and CGMP compliance processes in its statements to investors, including specifically through detailed data it received from the Quality Council. For instance, in a 2018 report, Mylan assured investors that it had “global systems and processes in place to

provide our people with the foundation and tools needed to maintain an effective quality management system . . . . Our Quality Council program provides management with clear, quantitative data, including that of key performance indicators. It also tracks and analyzes quality trends, reviews inspection results and identifies potential areas for employee training.” Accordingly, Defendants Bresch, Malik, Mauro, and Parks, either exercised the oversight they claimed, in which case they were amply informed about Morgantown’s CGMP failures, or they failed to exercise that oversight, in which case Defendants’ statements were reckless, at a minimum.

831. Moreover, the Individual Defendants had additional access to data relating to failed quality control testing through Mylan’s TestTrack system. As alleged above, data relating to failed quality testing results were contemporaneously recorded in TestTrack, and showed, among other things, an enormous backlog of unresolved investigations, repeated invalidation of failing results for stock reasons (such as “dirty glassware”), and repeated re-testing of failing results without documentation of any investigation into the failures.

832. Fourth, the egregiousness, scope, and duration of Morgantown’s CGMP and data integrity failures supports an inference of scienter, particularly since the FDA had warned Mylan that the very same violations affected other Company facilities. As alleged above, Mylan’s improper quality testing and assurance practices contravened core CGMP regulations and industry standards, notwithstanding Defendants Bresch, Malik, Mauro and Parks’ assurances that Mylan’s facilities were not only meeting, but exceeding, both. As both the FDA and commentators have explained, Mylan’s CGMP failures were not minor or arcane, but, rather, were blatant and pervasive, and, therefore, could not reasonably have escaped management’s notice. And as FDA whistleblowers and Former Employees explained, these glaring deficiencies

were pervasive throughout Morgantown, and throughout several other Mylan facilities, for years, even before the start of the Relevant Period.

833. In meetings with, and reports issued to, Mylan, the FDA characterized the Company's CGMP violations as "egregious," "stun[ing]," and "significant," and told Defendant Malik that they led the agency to question whether the Company was being "transparent at all of its sites." Following public disclosure of Morgantown's CGMP failures, analysts and industry commentators likewise noted the violations were exceedingly serious. For instance, Leerink analysts stated in a January 2019 report that the CGMP failures cited by the FDA "raise concerns around patient safety and product quality and thus will require extensive actions to correct" and that a specialist they consulted noted "the severity" of the violations and "was not surprised that Mylan received a Warning Letter."

834. Indeed, Mylan did not merely perform shoddy or subpar quality testing at Morgantown; it failed to perform any quality testing of at least 95% of the drug products manufactured there and, in many cases, tested equipment no more than once a year, directly contrary to Defendants' public statements.

835. Likewise, Mylan did not merely ignore quality assurance standards, it actively bypassed and subverted key FDA-mandated safety testing. For instance, the FDA repeatedly warned Defendants that Mylan routinely tested drug products and equipment into compliance at Morgantown, in contravention of numerous well-established regulatory requirements and longstanding agency guidance singling this practice out for censure as "unscientific and objectionable under CGMPs." Similarly, the FDA warned Mylan that the Company had engaged in a host of suspect data practices, including repeatedly misstating investigative findings, altering drug samples, "improperly invalidat[ing]" reports of defects and failing quality testing results,

and “preinjecting” batch samples. Indeed, Mylan itself acknowledged in private correspondence with the FDA that the agency’s 2016 findings “raised questions regarding our laboratory testing and the validity of the data generated to support our product on the market.” As Mylan well knew, other drug makers found to have similarly violated data integrity requirements were required to undergo extensive remediation and suffered severe business disruptions as a result. Indeed, these violations were so serious that the FDA’s Commissioner took the unusual step of personally tweeting out the FDA’s 2018 warning letter to Mylan recounting some of them.

836. Further, as the FDA pointed out, Mylan’s CGMP and data integrity failures were extremely serious because they demonstrably jeopardized patient safety, leading to the release of adulterated and contaminated drug products to the public. Indeed, as discussed above, Mylan was forced to recall dozens of drugs manufactured at Morgantown during the Relevant Period as a direct result of the Company’s egregious CGMP and data integrity failures.

837. In addition, as the FDA also repeatedly made clear, Mylan’s “senior management” was directly responsible for, and implicated in, the Company’s CGMP failures. In the 2018 Form 483, the FDA excoriated “Senior Management” for failing to “ensure continuing suitability and effectiveness of quality systems through governance” and cited “numerous instances of a lack of appropriate oversight by the Quality Unit and a failure to follow” Mylan’s own operating procedures. Likewise, the Morgantown warning letter explained, “Your firm lacks an adequate ongoing program for monitoring process control to ensure stable manufacturing operations and consistent drug quality . . . . When significant variability is observed in one or more stages of pharmaceutical production, it is essential for executive management to support and implement effective actions that proactively address the source(s) of the variation and provide for a continued state of control . . . . Your lack of rigorous oversight of manufacturing

changes continues to be a major factor in the unexpected variation observed in your drug products.” Similarly, Leerink analysts noted in their January 2019 report that the specialist they consulted “was not surprised that Mylan received a Warning Letter especially given that inadequacies of the quality control unit was designated as Observation #1.”

838. As the FDA pointed out, Mylan had received repeated warnings about these same serious violations—including widespread testing into compliance—at several other facilities, including Nashik and at least three other sites Mylan had acquired prior to the Relevant Period. These allegations support an inference that, at a minimum, Defendants recklessly disregarded that these serious CGMP failures pervaded Morgantown, one of the Company’s most significant manufacturing sites. As the FDA concluded in the Morgantown warning letter, “These repeated failures at multiple sites demonstrate that Mylan’s management oversight and control over the manufacture of drugs is inadequate . . . . Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.”

839. Accordingly, the magnitude and pervasiveness of the deficiencies in Mylan’s quality control processes and CGMP compliance, and the length of time those deficiencies went unaddressed, further support an inference that Defendants’ repeated statements touting the Company’s quality control processes and manufacturing capabilities were made either in a deliberate attempt to deceive or in reckless disregard of obvious facts.

840. Fifth, Morgantown’s profound CGMP failures were pervasive and widely known throughout Mylan, which supports an inference of Defendants’ scienter. As described above, numerous Former Employees and FDA reports not only confirmed that the CGMP and data integrity failures that the FDA identified at the Company were egregious and systemic, but also that they were widespread throughout Mylan’s facilities and widely known by Company

personnel. For instance, according to the Amended Complaint in the W.D. Pa. Mylan Class Action, FE6 reported that even prior to the start of the Relevant Period, senior Mylan executives, including Mylan’s Vice President of Operations, the Head of the Morgantown facility, and the Heads of Quality and Manufacturing at Morgantown, knew and routinely discussed that it was impossible for Morgantown to both meet the facility’s outsized production demands and satisfy its CGMP compliance and product quality obligations.

841. Likewise, according to the Amended Complaint in the W.D. Pa. Mylan Class Action, FE1 recalled reporting both Morgantown’s failure to test the majority of its manufactured drugs and equipment and Mylan’s practice of “testing into compliance” to FE1’s superiors, including Morgantown’s Head of Quality, Kim Kupec, and the Senior Director of Quality Assurance Operations, Eddie Koski, in meetings in 2015 and 2016, but FE1’s concerns were ignored. FE2 similarly described that, from prior to the Relevant Period until April 2018, testing into compliance was widespread at the Morgantown facility and conducted at the express direction of FE2’s supervisors in the Quality Assurance division. FE4 also described the practice of “testing into compliance” as “commonplace” throughout Mylan during FE4’s tenure with the Company. FE5 noted that the practice of testing into compliance was not only prevalent at Morgantown, but also at Mylan’s sites in Nashik and Bangalore, India.

842. According to the Amended Complaint in the W.D. Pa. Mylan Class Action Former Employees similarly described other suspect practices—including “preinjecting” data samples and “crashing files” to avoid recording bad results—as widespread throughout Mylan’s facilities. FE1 explained that improperly re-injecting drug samples into gas chromatographs prior to official analyses was a widespread practice at Morgantown, which continued but “became more covert” after the FDA issued the 2016 Form 483. FE1 also explained that employees at

Morgantown consistently cut the power to their computers to crash them when their computers showed that analyses were failing; this practice allowed analysts to void any record of a failing test result. FE2 confirmed that FE2 and other technicians received instructions from their supervisors to abort analyses this way when OOS results were imminent.

843. According to the Amended Complaint in the W.D. Pa. Mylan Class Action, Mylan Former Employees also explained that instances of cross-contamination and egregious cleaning violations were widespread and numerous throughout Mylan's facilities. FE1 recalled repeatedly raising issues of cross-contamination—in which drugs were contaminated with residue from drugs previously manufactured on the same equipment—with FE1's superiors, but no meaningful remedial measures were ever implemented. FE3 agreed, noting that because Mylan failed to test the vast majority of the drug products manufactured at Morgantown, numerous rooms within the facility were visibly cross-contaminated (which the FDA also observed and cited).

844. Finally, the Amended Complaint in the W.D. Pa. Mylan Class Action indicates that Former Employees of Mylan described that it was common knowledge within the Company that Mylan's overwhelming production volume prevented Morgantown personnel from meaningfully investigating failing quality tests. For instance, FE3 explained that only 3% to 5% of the drugs manufactured at Morgantown were actually subject to product quality testing during FE3's tenure because the enormous production volume flowing through the facility made more comprehensive testing impossible. FE1 agreed, reporting that, beginning in the late 2000's and through the remainder of FE1's tenure at the Company, Mylan performed product quality testing on no more than 5% of the drugs manufactured at Morgantown because production demands made broader testing impossible. FE4 similarly described that, because Mylan's production

volume was so high, Morgantown personnel lacked the time and resources to meaningfully investigate failing quality tests. In fact, at the close of the Relevant Period, Mylan’s Head of Global Quality admitted to these widespread failings, writing in a letter to the FDA following the 2018 Form 483, “We believe that the large volume of doses and products within the Morgantown portfolio, while it has enabled us to supply the US market with products manufactured in the US, has inhibited [Mylan’s] ability to achieve the high level of control over our manufacturing processes that we expect.”

845. Sixth, Mylan’s quality control processes and CGMP compliance were an area of significant regulatory scrutiny, which further supports an inference of Defendants’ scienter. As described above, because Mylan is subject to strict regulatory control, Defendants were familiar, and had extensive experience, with the FDA’s inspection and citation process. As discussed above, the FDA inspected Mylan’s facilities and inspectors reported regulatory violations to Mylan’s management. In particular, and as Mylan knew, enforcement of data integrity standards was a subject of outsized concern at the FDA at the outset of the Relevant Period. As alleged above, the FDA has emphasized that companies that violate CGMP and data integrity requirements face severe sanctions. Moreover, several drug manufacturers found to have violated data integrity requirements, including the FDA’s clear proscriptions against testing into compliance, have experienced serious adverse consequences as a result. These consequences included severe and prolonged production disruptions, significantly increased operating costs driven by extensive remediation requirements, and freezing of new drug approvals.

846. The experience that Mylan’s executives had with the FDA’s inspection and citation process—which consistently resulted in findings of CGMP and data integrity violations across numerous Mylan facilities and the issuance of citations to the Company—supports the

inference that Defendants' statements regarding Mylan's compliance with CGMP and data integrity regulations were at least recklessly false when made.

847. Seventh, the significance of the Morgantown facility to Mylan's profitability, operational capacity, and overall financial wellbeing supports an inference of Defendants' scienter. The Morgantown campus is Mylan's largest and most significant facility in the United States; in fact, it is one of the largest pharmaceutical manufacturing facilities in the entire United States. Mylan highlighted Morgantown as a "significant" manufacturing facility in its Forms 10-K filed throughout the Relevant Period. In a January 2019 analyst report, Leerink noted that the Morgantown facility produced approximately 85% of the oral solid doses of drugs (the dominant form of dosage) Mylan sold in the United States, approximately 17 billion doses. Indeed, Defendant Malik has personally admitted that Morgantown was "significant for us." The fact that the egregious CGMP and data integrity violations described in this Complaint were, for years, rampant at Mylan's largest and most significant manufacturing facility—the plant producing the vast majority of the drugs Mylan sold—supports the inference that Defendants' statements and omissions minimizing or outright hiding those CGMP and data integrity violations were knowingly false when made.

848. Eighth, that Defendants' false and misleading statements about Mylan's product quality and operating capacity concerned one of the most significant issues and gravest risks facing the Company during the Relevant Period further bolsters the inference of scienter. As alleged above, CGMP and data integrity compliance was essential to Mylan's ability to market its drugs and, therefore, of critical importance to investors. As discussed above, the FDA has repeatedly warned that companies violating CGMP and data integrity standards face severe sanctions. Moreover, numerous drug makers found to have violated these have experienced

significant disruption to production, product approval, and greatly increased operating costs driven by expensive remediation. Indeed, Mylan itself acknowledged that “[f]ailure to comply with CGMP” could result in a host of adverse regulatory and business consequences, including “warning letter[s], fines, penalties, disgorgement, unanticipated compliance expenditures,” product recalls, and even criminal prosecution. Accordingly, Defendants issued numerous public statements touting Mylan’s rigorous product quality processes as a key “strength,” value driver, and competitive advantage. And when news of the Nashik warning letter became public, analysts and investors sought, and received, numerous reassurances from Defendants about Mylan’s CGMP compliance.

849. Likewise, in direct response to analyst questions throughout the Relevant Period about how Mylan was weathering an unfavorable pricing environment, Defendants repeatedly—almost unfailingly—cited the Company’s vast operating capacity as a key differentiator that allowed the Company to attract customers and react opportunistically to market shortages. For instance, at the June 2016 Goldman Sachs Healthcare Conference, Defendant Bresch told investors, “It’s always been a volume-driven business, always . . . [T]here’s a much—more of a sense from our customer base that having a reliable global supply chain is important, that they don’t want to have to turn customers away because of products—they’re not able to get their hands on a product.” Thus, the integrity of Mylan’s operating platform and the Company’s ability to reliably produce industry-leading volume “all to stringent quality standards,” as Defendants claimed was of utmost importance to investors.

850. Accordingly, the fact that Defendants’ misstatements concerned some of the most significant issues and risks facing Mylan during the Relevant Period, supports an inference of

severe recklessness at a minimum, particularly given the numerous warnings concerning egregious CGMP failures Defendants received.

851. Ninth, Defendant Malik’s experience and tenure at Ranbaxy—a generic drug manufacturer that was rocked by scandals stemming from CGMP and data integrity violations that mirrored those that plagued Mylan during the Relevant Period—supports an inference of Defendant Malik’s scienter. Throughout a seventeen-year career at Ranbaxy, Defendant Malik was intimately involved in Ranbaxy’s CGMP and data integrity violations. As described above, shortly after Defendant Malik’s departure from Ranbaxy, a whistleblower reported to the FDA that the company had fabricated data concerning 200 products sold across 40 countries over the course of two decades—Defendant Malik’s entire tenure at the company—and that the company’s practice of forging data, lying to regulators, and endangering patients was “common knowledge” within the company. The whistleblower’s report led to an FDA investigation, an armed raid on Ranbaxy’s New Jersey headquarters, and the issuance of two warning letters to Ranbaxy. This supports the inference that Defendant Malik was instrumental in fostering the culture at Mylan under which such failures became the norm. At the very least, Defendant Malik was reckless in turning a blind eye to the growth of such a culture: as his experience at Ranbaxy makes clear, Defendant Malik knew CGMP and data integrity failures when he saw them.

852. Tenth, Defendants Bresch and Parks also knew about, or recklessly disregarded, Mylan’s ineffective disclosure controls and procedures. The glaring holes in Mylan’s disclosure controls and procedures – many of which are addressed in the Corporate Integrity Agreement that Mylan entered into in connection with the DOJ settlement – were the responsibility of Mylan’s senior executives. Indeed, Defendants Bresch and Parks both attested that they had designed Mylan’s disclosure controls and procedures (or had caused such disclosure controls and

procedures to be designed under their supervision), and that they had each evaluated the effectiveness of Mylan's disclosure controls and procedures before certifying to their effectiveness.

#### **NO SAFE HARBOR**

853. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Mylan who knew that the statement was false when made.

#### **PRESUMPTION OF RELIANCE**

854. Plaintiffs intend to rely upon the presumption of reliance established by the fraud on-the-market doctrine in that, among other things: (a) Defendants made public misrepresentations or failed to disclose material facts during the relevant time period; (b) the omissions and misrepresentations were material; (c) Mylan common stock traded in an efficient market; (d) the misrepresentations alleged would tend to induce a reasonable investor to

misjudge the value of Mylan common stock; and (e) the Plaintiffs purchased Mylan common stock between the time Defendants misrepresented or failed to disclose material facts and the time when the true facts were disclosed, without knowledge of the misrepresented or omitted facts, and in reliance on the integrity of the market for Mylan stock.

855. At all relevant times, the market for Mylan common stock was efficient for the following reasons, among others:

- (a) Mylan stock met the requirements for listing, and was listed and actively traded on NASDAQ, a highly efficient and automated market;
- (b) As a regulated issuer, Mylan filed periodic public reports with the SEC and NASDAQ;
- (c) Mylan regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- (d) Mylan was followed by several securities analysts employed by major brokerage firm(s) who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace.

856. As a result of the foregoing, the market for Mylan common stock promptly digested current information regarding Mylan from all publicly available sources and reflected such information in the prices of the stock.

857. Under these circumstances, a presumption of reliance applies.

858. Plaintiffs are also entitled to a presumption of reliance under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972) because Plaintiffs' claims are, in large part, grounded on Defendants' material omissions. Insofar as this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery.

#### **ACTUAL RELIANCE**

859. Plaintiffs and/or their investment managers acting on their behalf, actually, reasonably, and justifiably relied upon Defendants' misleading statements by, *inter alia*: (1) reading Mylan's SEC filings, including without limitation, annual reports filed on Form 10-K, quarterly reports filed on Form 10-Q, and current reports filed on Form 8-K; (2) reading analyst reports regarding Mylan; (3) reading newspaper and other media accounts regarding Mylan; and (4) listening to, or reading the transcripts of, earnings conference calls, and other investor presentations by Mylan management.

860. In reliance on Defendants' misleading statements and/or omissions, Plaintiffs purchased Mylan common stock after each of the misleading statements alleged herein during the Relevant Period.

861. Plaintiffs would not have acquired Mylan common stock, nor would Plaintiffs have the prices they paid for such stock – which were inflated by Defendants' misconduct – had they known the truth about the matters alleged herein.

862. In purchasing Mylan's common stock, Plaintiffs actually and justifiably read, and had direct eyeball reliance on, Mylan's 2016 Annual Report, 2017 Annual Report, 2018 Annual Report, 2019 Annual Report, and 2018 First Quarter Report.

**COUNT ONE**

**For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated  
Thereunder  
(Brought by Plaintiffs Against All Defendants)**

863. Plaintiffs repeat and reallege each and every allegation above as if fully set forth herein.

864. During the Relevant Period, Defendants made, disseminated, or approved the false and misleading statements specified above. Defendants knew that such statements, when made, were false and misleading, or were reckless in their disregard as to the truth of such statements, which contained material misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

865. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

866. employed devices, schemes, and artifices to defraud;

867. made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or

868. engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs in connection with their purchases of Mylan securities during the Relevant Period.

869. Plaintiffs have suffered damages in that, in reliance on Defendants' statements and/or the integrity of the market, they paid artificially inflated prices for Mylan's securities. Plaintiffs would not have purchased such securities at the prices they paid, or at all, if they had

been aware that the market prices of such securities had been artificially and falsely inflated by Defendants' misleading statements.

870. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs suffered harm in connection with their respective purchases of the Company's stock during the Relevant Period.

871. By virtue of the foregoing, Defendants' violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

## COUNT TWO

### For Violation of Section 20(a) of the Exchange Act (Brought by Plaintiffs Against the Individual Defendants)

872. Plaintiffs repeat and reallege the above paragraphs as though fully set forth herein.

873. The Individual Defendants acted as controlling persons of Mylan within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

874. In particular, each of the Individual Defendants Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, each is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

875. As set forth above, Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs suffered harm in connection with their respective purchases of the Company's stock during the Relevant Period.

### **COUNT THREE**

#### **For Violations of Section 18 of the Exchange Act** **(Brought by Plaintiffs Against Defendants Bresch and Parks)**

876. Plaintiffs repeat and reallege the above paragraphs as though fully set forth herein.

877. As alleged herein, Defendant Bresch caused statements to be made in Mylan's 2016 Annual Report, and the SOX certifications filed with that Report, that were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

878. As alleged herein, Defendants Bresch and Parks caused statements to be made in Mylan's 2017 Annual Report, and the SOX certifications filed with that Report, that were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

879. As alleged herein, Defendant Bresch caused statements to be made in Item 4 of, and the SOX certifications filed with, Mylan's Quarterly Report for the First Quarter of 2016 that

were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

880. As alleged herein, Defendants Bresch and Parks caused statements to be made in Item 4 of, and the SOX certifications filed with, Mylan's Quarterly Report for the Second Quarter of 2016 that were, at the time and in light of the circumstances under which they were made, false or misleading with respect to material facts.

881. In purchasing Mylan's common stock, Plaintiffs actually and justifiably read, and had direct eyeball reliance on, Mylan's 2016 Annual Report, 2017 Annual Report, Quarterly Report for the First Quarter of 2016, and Quarterly Report for the Second Quarter of 2016.

882. In ignorance of the falsity of Defendants' statements, or of the true facts, Plaintiffs purchased Mylan common stock in actual, justifiable, eyeball reliance upon Defendants' representations.

883. Defendants' materially false and misleading statements and omissions of material fact artificially inflated the price of Mylan common stock.

884. Had they known the true facts, Plaintiffs would not have purchased Mylan common stock and/or would not have purchased the shares at the inflated prices they paid.

885. Upon disclosure of the true facts, the price of Mylan common stock dropped, and Plaintiffs suffered damages in an amount to be proven at trial.

886. By reason of the foregoing, Defendants Bresch and Parks, are liable to Plaintiffs for violations of Section 18 of the Exchange Act, 15 U.S.C. § 78r.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Awarding compensatory damages in favor of Plaintiffs against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon interest thereon;

B. Awarding Plaintiffs their reasonable costs and expenses incurred in this Action, including counsel fees and expert fees; and

C. Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiffs hereby demand a trial by jury as to all issues so triable.

Dated: February 15, 2021

**KIRBY McINERNEY LLP**

By: /s/ Daniel Hume  
Daniel Hume  
Ira M. Press  
Meghan J. Summers  
250 Park Avenue, Suite 820  
New York, New York 10177  
Telephone: (212) 371-6600  
Facsimile: (212) 751-2540  
dhume@kmllp.com  
ipress@kmllp.com  
msummers@kmllp.com

**BRAGAR EAGEL & SQUIRE, P.C.**  
J. Brandon Walker  
Melissa A. Fortunato  
810 Seventh Avenue, Suite 620  
New York, NY 10019  
Facsimile: (212) 214-0506  
Telephone: (212) 308-5858  
walker@bespc.com  
fortunato@bespc.com

**STURMAN LLC**  
Deborah Sturman  
600 Third Avenue, Suite 2101

New York, New York 10016  
Telephone: (212) 367-7017  
Facsimile: (917) 546-2544  
Sturman@Sturman.ch